

**BỘ Y TẾ**  
**BỆNH VIỆN PHỔI TRUNG ƯƠNG**

**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM**  
**Độc lập - Tự do - Hạnh phúc**

Số: 1010 /BVPTU – CTCLQG  
V/v: Điều chỉnh Hướng dẫn mua dịch vụ  
xét nghiệm HIV năm 2023  
**KHẨN**

Hà Nội, ngày 18 tháng 4 năm 2023

**Kính gửi:** - Chương trình chống lao 63 tỉnh/tp;  
- Bệnh viện 71 Trung ương; Bệnh viện 74 Trung ương;  
- Bệnh viện Phổi Trung ương – Khoa Dược, Phòng TCKT.

Tiếp theo công văn số 819/BVPTU- CDCT ngày 03/04/2023, Bệnh viện Phổi Trung ương – Chương trình Chống lao Quốc Gia ( BVPTU – CTCLQG) xin thông báo với các đơn vị như sau:

- Đề nghị các đơn vị thực hiện mua test nhanh HIV theo “**Danh sách các bộ sinh phẩm xét nghiệm HIV theo Chính sách đảm bảo chất lượng của Quỹ Toàn Cầu - Bản cập nhật ngày 29/03/2023**” đính kèm sau công văn.
- Đề nghị các đơn vị quản lý, báo cáo tình hình sử dụng test nhanh 6 tháng/ lần; 1 năm/ 2 lần theo quy định và theo biểu mẫu đính kèm.

**❖ Các thông tin về kỹ thuật xin vui lòng liên hệ:**

- Bác sỹ Nguyễn Văn Cử theo số điện thoại: 0912170933 hoặc qua email: cu\_nguyen\_van@yahoo.com;
- Bác sỹ Nguyễn Văn Phẩm theo số điện thoại: 0904273601 hoặc qua email: bsphambyt@gmail.com
- Các thông tin về thủ tục thanh quyết toán xin vui lòng liên hệ: với bộ phận Tài chính Kế toán của Chương trình Chống lao Quốc Gia qua email: bvpqtc@gmail.com.

Trân trọng kính chào.

**Nơi nhận:**

- CTCL các tỉnh/tp.
- Đơn vị: KT;
- KT QTC;
- Đơn vị CLKHHC(HA 02);
- Lưu: VT.

**GIÁM ĐỐC**



**Đinh Văn Lượng**

Product name

## 144

1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 2679, 26

| Eligibility<br>and or other comments |
|--------------------------------------|
| WHO PQ                               |
| WHO PQ                               |
| WHO PQ                               |
| WHO PQ                               |

# HIV Simple Assays / Rapid Diagnostic Tests (RDTs) (not intended to be used as a donor screening tests - unless otherwise specified)

\* (see) mark indicates that product is WHO prequalified

| Manufacturer Product Catalogue number | Product Name                                        | Number of tests per kit | Initial Sensitivity | Final Specificity | Manufacturer                                     | Analysis                                                                            | Specimen Type            | Antibody window / Storage temperature | Comments                                                                                                                                              | 15 Gally WHO or GHTT countries |
|---------------------------------------|-----------------------------------------------------|-------------------------|---------------------|-------------------|--------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 7D2846                                | Alero HIV Combo                                     | 20                      | 100%                | 99.75%            | Abbott Alere Medical Co. Ltd, Marnoo, Japan      | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 15 months<br>2 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips | GHTT (CB mark)                 |
| 7D2847                                |                                                     | 100                     |                     |                   |                                                  |                                                                                     |                          |                                       |                                                                                                                                                       |                                |
| 7D2842 *                              | Determine HIV Early Detect (former Alera HIV Combo) | 20                      | 100%                | 99.40%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 18 months<br>2 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips | WHO PQ                         |
| 7D2843 *                              | Determine HIV Early Detect (former Alera HIV Combo) | 200                     | 100%                | 99.40%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 18 months<br>2 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips |                                |
| 7D2845 ET *                           | Determine HIV Early Detect (former Alera HIV Combo) | 100                     | 100%                | 99.40%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 18 months<br>2 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips |                                |
| 7D2845 STS *                          | Determine HIV Early Detect (former Alera HIV Combo) | 100                     | 100%                | 99.40%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 18 months<br>2 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips |                                |
| 02FK17 *                              | BioLine HIV-1/2 3.0                                 | 5/5                     | 99.80%              | 99.90%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 24 months<br>1 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips | WHO PQ                         |
| 02FK18 *                              |                                                     | 3/5                     |                     |                   |                                                  |                                                                                     |                          |                                       |                                                                                                                                                       |                                |
| 02FK19 *                              | BioLine HIV-1/2 3.0                                 | 30                      | 99.80%              | 99.90%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 24 months<br>1 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips | WHO PQ                         |
| 02FK19 *                              | BioLine HIV-1/2 3.0                                 | 30                      | 99.80%              | 99.90%            | Abbott Diagnostic Medical Co. Ltd, Marnoo, Japan | Differentiation between HIV 1/2 antibodies combined detection and HIV-1 p24 antigen | Serum/Plasma/Whole Blood | 24 months<br>1 to 30°C                | If whole blood: lancets, alcohol swabs, chase buffer (7D2843), EDTA capillary tubes (7D2842)<br>If serum/plasma: requires precision pipette plus tips |                                |
| 2901AW20                              | Paide HIV Verification Test                         | 20                      | 100%                | 99.75%            | Abbott Rapid Diagnostics, Jena GmbH, Germany     | Differentiation between HIV 1/2 antibodies                                          | Serum/Plasma/Whole Blood | 24 months<br>2 to 30°C                | sterile disposable lancets, alcohol swabs, chase buffer                                                                                               | WHO PQ                         |

HIV Simple assays/Rapid Diagnostic Tests (RDTs) can be used as a donor screening test – unless other

(star) mark indicates that product is WBO p-qualified.

| Manufacturer's product number | Product Name                                                                          | Number of tests per kit | Initial Sensitivity | Final Specificity | Manufacturer                                     | Analyte                               | Specimen Type                | Anticardiolipin (cardiolipin) Storage Temperature | Comments                                                                                                    | Lab ID or CLIA# number |  |  |  |  |  |  |  |  |
|-------------------------------|---------------------------------------------------------------------------------------|-------------------------|---------------------|-------------------|--------------------------------------------------|---------------------------------------|------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------|--|--|--|--|--|--|--|--|
| WJ-1810 *                     | Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) | 107/kit                 | 100%                | 98.4%             | Beigun/Wentel Biological Pharmacy Enterprise Co. | HIV 1/2 antibodies combined detection | Serum / Plasma / Whole Blood | 15 months<br>2 to 30 °C                           | For accessories see IFU                                                                                     | WH-D-PQ                |  |  |  |  |  |  |  |  |
| WJ-1810E *                    |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EL *                   |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810L *                    |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EEL *                  |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EL *                   |                                                                                       | 501/kit                 |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810L *                    |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EEL *                  |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EL *                   |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| WJ-1810EL *                   |                                                                                       |                         |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| 90-1020 *                     | INSTI HIV-2/HIV-2 Antibody Test Kit                                                   | 24                      | 100%                | 99.70%            | Biological Laboratories, Richmond, Canada        | HIV 1/2 antibodies combined detection | Serum / Plasma / Whole Blood | 15 months<br>15 to 30 °C                          | 24 T/kit at<br>T/kit with support materials.<br>If 90-1020 kit, use alcohol swab, pipette pipette plus tips | WH-D-PQ                |  |  |  |  |  |  |  |  |
| 90-1013 *                     |                                                                                       | 24                      |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| 90-1009 *                     |                                                                                       | 48                      |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| 90-1022 *                     |                                                                                       | 48                      |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| 90-1028 *                     |                                                                                       | 48                      |                     |                   |                                                  |                                       |                              |                                                   |                                                                                                             |                        |  |  |  |  |  |  |  |  |
| 90-1064 *                     |                                                                                       | 48                      |                     |                   |                                                  |                                       |                              |                                                   | Support material: none                                                                                      |                        |  |  |  |  |  |  |  |  |

# HIV Simple Assays / Rapid Diagnostic Tests (RDTs) (not intended to be used as a donor screening tests – unless otherwise specified)

| Product codes are encrypted with a * (star) to indicate that product is WHO prequalified |                                  |                         |                                                                                                                                                             |                                               |                                                                        |                                       |                                                                    |                              |                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------|----------------------------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer Product number                                                              | Product Name                     | Number of tests per kit | Initial Sensitivity                                                                                                                                         | Final Specificity                             | Manufacturer                                                           | Age/sex                               | Specimen Type                                                      | Assigned storage temperature | Comments                                                                                                                                                                                                                                                                                                                                                                                                         | Labeling: WHO or CE mark                                                                                                                                                                                            |
| 72330 *                                                                                  | Genie Fast HIV 1/2               | 30                      | 100%                                                                                                                                                        | 99.90%                                        | Bio-Rad Laboratories, Marnes La Coquette France and Steinsbois, France | HIV 1/2 antibodies (group M and O)    | Serum/Plasma/Venous and Capillary Whole Blood                      | 18 months 2 to 30°C          | with support materials: ethanol and disposable pipettes with support materials: alcohol, disposable pipettes, microtubes, lancets, scratch swabs                                                                                                                                                                                                                                                                 | WHO PQ                                                                                                                                                                                                              |
| 72327 *                                                                                  |                                  | 25                      |                                                                                                                                                             |                                               |                                                                        |                                       |                                                                    |                              |                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                     |
| 72347 *                                                                                  |                                  | 25                      |                                                                                                                                                             |                                               |                                                                        |                                       |                                                                    |                              |                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                     |
| 857318                                                                                   | EXACTO® PRO TEST HIV             | 10                      | 99.9%                                                                                                                                                       | 99.9%                                         | Biogenex SA, Brive-la-Gaillarde, France                                | HIV 1/2 antibodies combined detection | Serum/Plasma/Venous whole blood/Fingerstick Whole Blood/Oral Fluid | 24 months 2 to 30°C          |                                                                                                                                                                                                                                                                                                                                                                                                                  | GHF (CE mark)                                                                                                                                                                                                       |
| 69-9406-0 *                                                                              | DPP HIV 1/2 Assay                | 10                      | 99.8% HIV-1 (fingerstick whole blood) 99.9% HIV-1 (venous whole blood, serum, plasma) 98.9% HIV-1 (oral fluid) 100% HIV-2 (serum/plasma, blood, oral fluid) | 99.9% (serum/plasma, whole blood, oral fluid) | Chembio Diagnostic Systems, Medford, USA                               | HIV 1/2 antibodies combined detection | Serum/Plasma/Venous whole blood/Fingerstick Whole Blood/Oral Fluid | 24 months 2 to 30°C          | Lancet, 20-25 gauge, antiseptic wipes<br>Microcentrifuge container<br>For venipuncture whole blood collection and serum/plasma specimens:<br>Venipuncture apparatus and blood collection tubes<br>Precision pipette capable of delivering 50 µl of sample (each disposable tip) may be used in lieu of the disposable 50 µl sample loop supplied with the kit (for other than fingerstick whole blood specimens) | WHO PQ                                                                                                                                                                                                              |
| HIV903 *                                                                                 | HIV 1/2 STAT-PAX Diagnostik      | 30                      | 100%                                                                                                                                                        | 99.70%                                        | Chembio Diagnostic Systems, Medford, USA                               | HIV 1/2 antibodies combined detection | Serum/Plasma/Whole blood                                           | 24 months 5 to 30°C          | If whole blood: lancets, alcohol swabs<br>If alternative procedure must enter sample tubes and tube rack                                                                                                                                                                                                                                                                                                         | WHO PQ                                                                                                                                                                                                              |
| HIV101 *                                                                                 | HIV 1/2 STAT-PAX™                | 20                      | 99.90%                                                                                                                                                      | 100%                                          | Chembio Diagnostic Systems, Medford, USA                               | HIV 1/2 antibodies combined detection | Serum/Plasma/Whole blood                                           | 24 months 5 to 30°C          | If whole blood: lancets, alcohol swabs<br>HIV Test Kit: Control (HIV+/-) available                                                                                                                                                                                                                                                                                                                               | WHO PQ<br><a href="https://www.who.int/publications/m/item/WHO-PQ-2017-006-00_HIV_1-2_STAT-PAX_V2.0.pdf">https://www.who.int/publications/m/item/WHO-PQ-2017-006-00_HIV_1-2_STAT-PAX_V2.0.pdf</a><br>GHF (FDA, EMA) |
| HIV904 *                                                                                 | STRE CHECK® HIV 1/2 ASSAY        | 25                      | 99.8% (serum/plasma) 100% HIV-2 (serum/plasma)                                                                                                              | 99.9% (serum/plasma)                          | Chembio Diagnostic Systems, Medford, USA                               | HIV 1/2 antibodies combined detection | Serum/Plasma/Venous and Capillary Whole Blood                      | 24 months 5 to 30°C          | Lancet, sterile gauze, antiseptic wipes<br>Substrate: ethanol container<br>For venipuncture whole blood collection and serum/plasma specimens:<br>Venipuncture apparatus and blood collection tubes<br>Precision pipette capable of delivering 2 µl of specimen with disposable tips                                                                                                                             | WHO PQ<br>GHF (FDA, EMA)                                                                                                                                                                                            |
| 200740CB                                                                                 | "DIAGNOSTIC" HIV 1&2 Ab Cassette | 30                      | 100%                                                                                                                                                        | 100%                                          | Dialab GmbH, Austria                                                   | HIV 1/2 antibodies combined detection | Whole blood, Serum or Plasma                                       | 24 months 2 to 30°C          |                                                                                                                                                                                                                                                                                                                                                                                                                  | GHF (CE mark)                                                                                                                                                                                                       |

**HIV Simple assays/ Rapid Diagnostic Tests (RDTs)**  
(not intended to be used as a donor screening tests – unless otherwise specified)

| * (star) mark indicates that product is WHO prequalified |                        |                         |                     |                   |                                                                                                                    |                                       |                              |                                          |                                                                             |
|----------------------------------------------------------|------------------------|-------------------------|---------------------|-------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------------------|------------------------------------------|-----------------------------------------------------------------------------|
| Manufacturer's Product Catalogue number                  | Product Name           | Number of tests per kit | Initial Sensitivity | Final Specificity | Manufacturer                                                                                                       | Assay type                            | Specimen Type                | Anticipated shelf life (at 25°C storage) | Comments                                                                    |
| H18100                                                   | "DIAQUICK" HIV Plus    | 25                      | 100%                | 100%              | Diablot GmbH, Austria                                                                                              | HIV 1/2 antibodies combined detection | Serum or Plasma              | 24 months<br>2 to 30°C                   |                                                                             |
| H18101                                                   | "DIAQUICK" HIV Plus WB | 25                      | 100%                | 100%              | Diablot GmbH, Austria                                                                                              | HIV 1/2 antibodies combined detection | Whole blood, Serum or Plasma | 25 months<br>2 to 30°C                   |                                                                             |
| W0016-C4/P2                                              | "DIAQUICK" HIV Plus WB | 25                      | 100.0%              | 100.0%            | Guangzhou Wondfo Biotech Co. Ltd. 8 Lishiwan Road, Science City, Guangzhou District, Guangdong, 510663, P.R. China | HIV 1/2 antibodies combined detection | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  | Buffer solution included: 1 bottle x 5ml/bottle<br>Accessories not included |
| W0006-F004B5                                             |                        | 25                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-F0004b                                             |                        | 25                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-F00047                                             |                        | 25                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-F00048                                             |                        | 25                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-C4/P2-F                                            |                        | 40                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-P00049                                             |                        | 40                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-P00050                                             | Hexagon HIV            | 40                      | 100%                | 99.95%            | Humanase GmbH, Germany                                                                                             | HIV 1/2 antibodies combined detection | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  | Buffer solution included: 2 bottles x 5ml/bottle<br>Accessories: see IFU    |
| W0006-F00051                                             |                        | 40                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| W0006-F00052                                             |                        | 40                      |                     |                   |                                                                                                                    |                                       | Serum/Plasma/Whole Blood     | 24 months<br>2 to 30 °C                  |                                                                             |
| S7004P                                                   | Hexagon HIV            | 100                     | 100%                | 99.90%            | Humanase GmbH, Germany                                                                                             | HIV 1/2 antibodies combined detection | Whole blood, serum or plasma | 2 to 8°C                                 |                                                                             |

**HIV Simple assays/Rapid Diagnostic Tests (RDTs)**  
to be used as a donor screening tests – unless other

\* (aster) mark indicates that product is WTO prequalified

| Manufacturer Product Catalogue number | Tested Name                 | Number of tests per kit | Label Sensitivity | Test Specificity | Manufacturer                                                                                   | Analyte                                                                                                                                                                                                 | Specimen Type            | Antibody (duration) Storage temperature | Comments                                                                                                                                                                                                   | Abbott's view of CLIF results |
|---------------------------------------|-----------------------------|-------------------------|-------------------|------------------|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| ITPWOZIS-TC40                         | ONE STEP Anti-HIV(1&2) Test | 40                      | 100.0%            | 100.00%          | Latex PRODUCTS, INC.<br>332 Xingyang Road, Xinyang Ind Area, Henan, Xinyang 361022, P.R. China | HIV 1/2 antibodies combined detection                                                                                                                                                                   | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 | Accessories: plastic dropper (pipette), sample diluent (sample buffer), sterile safety lancets, alcohol swabs                                                                                              | W=O=EQ                        |
| ITPWOZIS-TC40                         | ONE STEP Anti-HIV(1&2) Test | 40                      | 100.0%            | 100.00%          | Latex PRODUCTS, INC.<br>332 Xingyang Road, Xinyang Ind Area, Henan, Xinyang 361022, P.R. China | HIV 1/2 antibodies combined detection                                                                                                                                                                   | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 | Accessories: plastic dropper (pipette), sample diluent (sample buffer), sterile safety lancets, alcohol swabs                                                                                              |                               |
| ITPWOZIS-TC25                         |                             | 25                      |                   |                  |                                                                                                |                                                                                                                                                                                                         | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 |                                                                                                                                                                                                            |                               |
| ITP0211-TC40                          | ONE STEP Anti-HIV(1&2) Test | 40                      | 99.8%             | 99.23%           | Latex PRODUCTS, INC.<br>332 Xingyang Road, Xinyang Ind Area, Henan, Xinyang 361022, P.R. China | HIV 1/2 antibodies combined detection                                                                                                                                                                   | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 | Accessories: plastic dropper (pipette)                                                                                                                                                                     | GHIF (CE mark)                |
| ITP0211-TC40                          | ONE STEP Anti-HIV(1&2) Test | 40                      | 99.8%             | 99.23%           | Latex PRODUCTS, INC.<br>332 Xingyang Road, Xinyang Ind Area, Henan, Xinyang 361022, P.R. China | HIV 1/2 antibodies combined detection                                                                                                                                                                   | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 | Accessories: plastic dropper (pipette), safety lancets, alcohol swabs                                                                                                                                      | GHIF (CE mark)                |
| ITP0211-TC40                          |                             | 10                      |                   |                  |                                                                                                |                                                                                                                                                                                                         | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 |                                                                                                                                                                                                            | GHIF (CE mark)                |
| HYVWP-01                              | MERISCREEN HIV 1-2 WB       | 36                      | 100%              | 100.00%          | Merit Diagnostics Pvt. Ltd.,<br>Wazir-Pg6, India                                               | HIV 1/2 antibodies combined detection                                                                                                                                                                   | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 | Cepheid Tubes,<br>Alcohol swabs and<br>lancets                                                                                                                                                             | GHIF (CE mark)                |
| HYVWP-02                              |                             | 40                      |                   |                  |                                                                                                |                                                                                                                                                                                                         | Serum/Plasma/Whole Blood | 24 months<br>2 to 30 °C                 |                                                                                                                                                                                                            |                               |
| 43030-020                             | Multisure HIV Rapid Test    | 30                      | 100%              | 99.12%           | MIP Biomedicals Asia Pacific<br>Singapore                                                      | Detected antibodies specific to HIV-1 gp120, HIV-1 gp41, HIV-1 p24 (also react with HIV-2) and HIV-2 p24 antigens in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulant | Serum/Plasma/Whole Blood | 24 months<br>2 to 28 °C                 | Additional devices which are necessary for performing this test are:<br>- lancets (skin prick to get the appropriate sample)<br>- alcohol swabs (disinfection of the skin prior to pricking)<br>- 2 lancet | GHIF (CE mark)                |

HIV Simple assays/Rapid Diagnostic Tests (RDTs) to be used as a donor screening tests – unless others

\* (error) marks indicates that produced by WZHO prequalification

| Manufacturer Product Catalogue number | Product Name                                     | Number of tests per kit | Batch Size/lot | Final Specification | Manufacturer                                                   | Assay type                                        | Specimen Type                        | Stability/Storage      | Comments                                                                                           | Logotype        |
|---------------------------------------|--------------------------------------------------|-------------------------|----------------|---------------------|----------------------------------------------------------------|---------------------------------------------------|--------------------------------------|------------------------|----------------------------------------------------------------------------------------------------|-----------------|
| SK4-0010                              | OneQuick HIV-1/2 - Rapid Antibody Test           | 110                     | 100%           | 99.90%              | OneQuick Technologies, Bechtel, USA (Manufactured in Thailand) | HIV-1/2 antibodies combined detection             | Serum/Plasma/Whole Blood/Coral Fluid | 30 months at 2 to 30°C | If whole blood, lancets, alcohol swabs, additional specimen bags (for 4-10) for specific bleeding. | WHO PQ          |
| SK4-0012                              |                                                  | 500                     |                |                     |                                                                |                                                   |                                      |                        |                                                                                                    |                 |
| SK4-0014                              |                                                  | 100                     |                |                     |                                                                |                                                   |                                      |                        |                                                                                                    |                 |
| SK4-0015                              |                                                  | 500                     |                |                     |                                                                |                                                   |                                      |                        |                                                                                                    |                 |
| SK4-0062 *                            | OneQuick ADVANCE Rapid HIV-1/2 Antibody Test     | 100                     | 99.30%         | 99.80%              | OneQuick Technologies, Bechtel, USA                            | HIV-1/2 antibodies combined detection             | Serum/Plasma/Whole Blood/Coral Fluid | 30 months at 2 to 30°C | If whole blood, lancets, alcohol swabs, additional specimen bags (for 4-10) for specific bleeding. | GHTF (GMA, PMA) |
| 1001-0079                             |                                                  | 25                      |                |                     |                                                                |                                                   |                                      |                        |                                                                                                    |                 |
| 1001-100/8                            |                                                  | 100                     |                |                     |                                                                |                                                   |                                      |                        |                                                                                                    |                 |
| 100FRC29CT                            | First Response HIV-1-2-0 Card Test               | 25                      | 100%           | 99.35%              | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | GHTF (CE mark)  |
| 100FRC30DE                            | First Response HIV-1-2-0 Card Test               | 30                      | 100%           | 99.35%              | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | GHTF (CE mark)  |
| 100FRC30S *                           | First Response HIV-1-2-0 Card Test (version 2.0) | 5                       | 100%           | 100.00%             | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | WHO PQ          |
| 100FRC30SCE                           | First Response HIV-1-2-0 Card Test (version 2.0) | 5                       | 100%           | 100.00%             | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | GHTF (CE mark)  |
| 100FRC30 *                            | First Response HIV-1-2-0 Card Test (version 2.0) | 10                      | 100%           | 100.00%             | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | WHO PQ          |
| 100FRC30CE                            | First Response HIV-1-2-0 Card Test (version 2.0) | 10                      | 100%           | 100.00%             | Premier Medical Corporation, Noida, India                      | Discrimination between HIV-1 and HIV-2 Antibodies | Serum/Plasma/Whole Blood             | 24 months at 2 to 30°C | If whole blood, lancets, alcohol swabs                                                             | GHTF (CE mark)  |

\* (star) in article indicates that product is WHO prequalified

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HIV Simple assays/Rapid Diagnostic Tests (RDTs) to be used as a donor screening tests – unless otherwise

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| Manufacturer<br>Product Catalogue<br>number | Product Name          | Number of<br>tests per kit | Initial Sensitivity | Final Specificity | Manufacturer                                           | Assay                                    | Specimen Type                      | Astoria®<br>Shelf-life<br>(months)<br>Storage Temperature | Comments                                                                                        | Stability<br>Viral or eITF activity |
|---------------------------------------------|-----------------------|----------------------------|---------------------|-------------------|--------------------------------------------------------|------------------------------------------|------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------|
| THI702                                      | Tigen Anti-HIV 1/2    |                            | 100%                | 100%              | Tekn Lab<br>Turkey                                     | HIV 1/2 antibodies<br>combined detection | Whole Blood,<br>Serum or<br>Plasma | 4 - 36 °C                                                 |                                                                                                 | CITEP (CE mark)                     |
| ESSE100                                     | TrinScreen HIV        | 100                        | 100%                | 100%              | Thermo Biorech Manufacturing<br>Ltd,<br>Bey, Ireland   | HIV 1/2 antibodies<br>combined detection | Whole Blood,<br>Serum or<br>Plasma | 24 months<br>2 - 30 °C                                    |                                                                                                 | WHO PQ                              |
| 1200502<br>+<br>1200502N+                   | Uni-Gold HIV          | 20                         | 99.80%              | 99.90%            | Tritity Biotech Manufacturing<br>Ltd,<br>Bics, Ireland | HIV 1/2 antibodies<br>combined detection | Serum/Plasma/<br>Whole Blood       | 20 months<br>2 to 27 °C                                   | Accuracy:<br>± 0.4 Weak Positive (5<br>mU/ml) and 2.0<br>Deposible Pipette                      |                                     |
| 1200607E                                    |                       |                            |                     |                   |                                                        |                                          |                                    |                                                           |                                                                                                 |                                     |
| 1200502N-120<br>1200602N-                   | Uni-Gold HIV          | 100                        | 99.80%              | 99.90%            | Tritity Biotech Manufacturing<br>Ltd,<br>Bics, Ireland | HIV 1/2 antibodies<br>combined detection | Serum/Plasma/<br>Whole Blood       | 20 months<br>2 to 27 °C                                   | Accuracy:<br>5 white Whole Reagent (2<br>ml) and 100<br>Disposable Pipettes                     | WAO PQ                              |
| *<br>1200502E-C                             |                       |                            |                     |                   |                                                        |                                          |                                    |                                                           |                                                                                                 |                                     |
| *<br>1200502E-C                             | Uni-Gold HIV Complete | 20                         | 99.80%              | 99.90%            | Tritity Biotech Manufacturing<br>Ltd,<br>Bics, Ireland | HIV 1/2 antibodies<br>combined detection | Serum/Plasma/<br>Whole Blood       | 20 months<br>2 to 27 °C                                   | Accuracy: 0.4 weak, 0.4 strong,<br>4 mild Weak Positive (2<br>ml) and 10<br>Disposable Pipettes |                                     |

N/A-NOT APPLICABLE

[illegible]

**List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy**

**HIV Self-Tests // Rapid Diagnostic Tests (RDTs)**  
**(not intended to be used as a donor-screening tests – unless otherwise specified)**

\* Product codes in parentheses (paren) with a (\*) mark, indicating that product is WHO prequalified

| Manufacturer Product Catalogue number                           | Product Name                                         | Number of tests per kit | Initial Sensitivity | Final Specificity | Manufacturer                                   | Assay                                 | Specimen Type | Archival stability (months) / Storage temperature | Comments                                                                        | Supplier WHO or other countries                                                                                                                                                               |
|-----------------------------------------------------------------|------------------------------------------------------|-------------------------|---------------------|-------------------|------------------------------------------------|---------------------------------------|---------------|---------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 29012-WHO *                                                     | CHEKNOVO HIV SELF-TEST                               | 1                       | 99.60%              | 98.50%            | Abbott Rapid Diagnostics (Australia)           | HIV 1/2 antibodies combined detection | Whole Blood   | 24 Months<br>2 to 30°C                            | (former E270 as RISK CATEGORY 2)                                                | WHO PQ<br><a href="https://extranet.who.int/pqweb/files/2017/04/RDXT_Anti-HIV-20170401.pdf">https://extranet.who.int/pqweb/files/2017/04/RDXT_Anti-HIV-20170401.pdf</a>                       |
| AKST001-13<br>AKST001-03-01<br>AKST001-03-02<br>AKST001-03-03 * | KoJian HIV Self-Test<br>(former Aluno HIV Self-Test) | 1                       | 99.80%              | 99.80%            | Aluno Diagnostics Pty Ltd, Taitheba, Australia | HIV 1/2 antibodies combined detection | Whole Blood   | 18 Months<br>2 to 30°C                            | (former E270 as RISK CATEGORY 2)                                                | WHO PQ<br><a href="https://extranet.who.int/pqweb/files/2017/04/RDXT_Anti-HIV-20170401.pdf">https://extranet.who.int/pqweb/files/2017/04/RDXT_Anti-HIV-20170401.pdf</a>                       |
| 90-1071 *                                                       | INSTI* HIV Self-Test                                 | 1                       | 99.80%              | 99.80%            | BioMérieux Laboratoire, Richmond, Canada       | HIV 1/2 antibodies combined detection | Whole Blood   | 12 Months<br>2 to 30°C                            | 270 as RISK CATEGORY 2 / Non-detection<br>Lateral flow required for procurement | WHO PQ<br><a href="https://www.who.int/diagnostics/assessments/evaluation/pq-criteria/pq-criteria.pdf">https://www.who.int/diagnostics/assessments/evaluation/pq-criteria/pq-criteria.pdf</a> |
| 85104                                                           | EXACTO® TEST HIV                                     | 1                       | on request          | on request        | BioMérieux SA, Strasbourg, France              | HIV 1/2 antibodies combined detection | Whole Blood   | 24 Months<br>1 to 30°C                            | 270 as RISK CATEGORY 2 / Non-detection<br>Lateral flow required for procurement | E270 until 10th January 2024                                                                                                                                                                  |
| 85109                                                           | EXACTO® TEST HIV DUO                                 | 2                       | on request          | on request        | BioMérieux SA, Strasbourg, France              | HIV 1/2 antibodies combined detection | Whole Blood   | 24 Months<br>1 to 30°C                            | 270 as RISK CATEGORY 2 / Non-detection<br>Lateral flow required for procurement | E270 until 10th January 2024                                                                                                                                                                  |
| 60-9908-D *                                                     | SURE CHECK HIV SELF-TEST                             | 1                       | 97.00%              | 100.00%           | Chembio Diagnostic Systems, Meriden, USA       | HIV 1/2 antibodies combined detection | Whole Blood   | 24 Months<br>1 to 30°C                            | 270 as RISK CATEGORY 2 / Non-detection<br>Lateral flow required for procurement | WHO PQ<br><a href="https://www.who.int/diagnostics/assessments/evaluation/pq-criteria/pq-criteria.pdf">https://www.who.int/diagnostics/assessments/evaluation/pq-criteria/pq-criteria.pdf</a> |

# HIV Self Tests / Rapid Diagnostic Tests (RDTs) (not intended to be used as a donor screening tests – unless otherwise specified)

\* (new) mark indicates that product is WHO prequalified

| Manufacturer Product Name | Product Name           | No. of tests per kit | Lot-to-lot Sensitivity | Final Specificity | Manufacturer                                                        | Analyte                               | Specimen Type | Antibody Stability / Storage Temperature | Comments                                                              | Regulatory Region                                                                                                                                                                                     |
|---------------------------|------------------------|----------------------|------------------------|-------------------|---------------------------------------------------------------------|---------------------------------------|---------------|------------------------------------------|-----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Wondfo P038 *             | Wondfo HIV Self-Test   | 1                    | 95.0%                  | 99.6%             | Guangzhou Wondfo Biotech Co., Ltd                                   | HIV 1/2 antibodies combined detection | Whole blood   | 24 Months at 20°C                        | Community Version<br>Individual Test pouches are labeled SK4-0004-### | WHO PQ                                                                                                                                                                                                |
| Wondfo P059 *             |                        | 25                   |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| Wondfo P060 *             |                        | 100                  |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-0004-### *            |                        | 1                    |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-1000-### *            | OneQuick HIV Self-Test | 50                   | 99.0%                  | 100.0%            | OneSure Technologies Inc, Bethlehem, USA (manufactured in Thailand) | HIV 1/2 antibodies combined detection | Oral fluid    | 30 Months at 20°C                        | Community Version<br>Individual Test pouches are labeled SK4-0004-### | WHO PQ<br><a href="https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf">https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf</a> |
| SK4-1001-### *            |                        | 250                  |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-2001-### *            |                        | 100                  |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-2001-### *            |                        | 1                    |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            | SK4-7000-350 *         | 50                   | 99.0%                  | 100.0%            | OneSure Technologies Inc, Bethlehem, USA (manufactured in Thailand) | HIV 1/2 antibodies combined detection | Oral fluid    | 30 Months at 20°C                        | Community Version<br>Individual Test pouches are labeled SK4-2001-### | WHO PQ<br><a href="https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf">https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf</a> |
| SK4-7000-350 *            |                        | 250                  |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            |                        | 50                   |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            |                        | 1                    |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            | SK4-7000-350 *         | 50                   | 99.0%                  | 100.0%            | OneSure Technologies Inc, Bethlehem, USA (manufactured in Thailand) | HIV 1/2 antibodies combined detection | Oral fluid    | 30 Months at 20°C                        | Community Version<br>Individual Test pouches are labeled SK4-2001-### | WHO PQ<br><a href="https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf">https://extranet.who.int/pqweb/rdt/art-at-3m-pvc-coupled-on-onequickself-test-v7.0.pdf</a> |
| SK4-7000-350 *            |                        | 250                  |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            |                        | 50                   |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |
| SK4-7000-350 *            |                        | 1                    |                        |                   |                                                                     |                                       |               |                                          |                                                                       |                                                                                                                                                                                                       |

HIV Self Tests / Rapid Diagnostic Tests (RDTs) should not be used as a donor screening tests—unless otherwise specified.

\*

Blindwater  
Product Catalogue  
multimedia

N/A- NOT APPLICABLE

Figure 1. The worldwide human population, by world region, and by population density, by world region, 1990-2000. The world population is projected to increase from 6.1 billion in 1990 to 9.1 billion in 2050. The world population is projected to increase from 6.1 billion in 1990 to 9.1 billion in 2050. The world population is projected to increase from 6.1 billion in 1990 to 9.1 billion in 2050.

Version 4B  
29 March 2023

Version 4B  
29 March 2023

Version 4B  
29 March 2023

Version 4B  
29 March 2023

HIV Enzyme immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – but for other uses specified)

\* Product codes are inscribed with a (date) mark in Vario grey on front

| Manufacturer<br>Product Catalogue<br>number | Product Name                              | Number of Tests<br>per Kit | Labelled description                                  | Final specificity                                      | Manufacturer                                                             | Analyte                                              | Analysis period (days)<br>Incubation<br>temperature | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Regulation<br>WHO or CE mark                                                              |
|---------------------------------------------|-------------------------------------------|----------------------------|-------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| 229152                                      | Vitrosabia HIV Ag/Ab                      | 576                        | 100.00%                                               | 99.50%                                                 | bioMérieux SA<br>69280 - Marcy l'Etoile / France<br>RCE LYON 673 640 399 | HIV-1/2 antibodies and HIV-1 p24 antigen             | 2 to 8°C                                            | Serum or plasma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CE mark                                                                                   |
| 72278                                       | Genscreen <sup>TM</sup> HIV s/z Version 2 | 96                         | 100%                                                  | 99.80%                                                 | Bio-Rad Laboratories, Marnes La<br>Cochette, France                      | HIV-1/2 antibodies combined<br>or discrimination     | 15 months<br>2 to 8°C                               | Serum and plasma specimen.<br>Preferable (gold test). EIA plus either EIA plus<br>inhibition, EIA plus in line, venous dilution system,<br>measuring optodes, (reagent bridge)                                                                                                                                                                                                                                                                                                                                                                                                                       | CE mark, TGA                                                                              |
| 72279                                       |                                           | 480                        |                                                       |                                                        | Bio-Rad Laboratories,<br>Stemwilde, France                               |                                                      |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
| 72366                                       | Genscreen <sup>TM</sup> UTI-TZA HIV Ag/Ab | 96                         | 100%                                                  | 99.20%                                                 | Bio-Rad Laboratories, Stemwilde,<br>France                               | HIV-1/2 antibodies combined<br>and HIV-1 p24 antigen | 15 months<br>2 to 8°C                               | Not suitable for whole blood<br>Requires EIA incubator,<br>washer, reader, precision<br>pipette plus 5% controlled<br>water.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | WHO PQ<br>http://bio.merieux.fr/produits/medicaments/72366/72366-ut-tza-hiv-ag-ab-v1.html |
| 72368                                       |                                           | 480                        |                                                       |                                                        |                                                                          |                                                      |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
| 21220                                       | Genscreen <sup>TM</sup> HIV-1 Ag Assay    | 108                        |                                                       | 99.35%                                                 | Bio-Rad<br>12240 Marne la Coquette - France                              | HIV-1 p24 antigen                                    | 1 month<br>2 to 8°C                                 | Human Serum, Plasma and Cell Culture Supernatant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | CE mark                                                                                   |
| 08217                                       | CS HIV Combo Ag/Ab EIA                    | 392                        | 100% (manual<br>method)<br>100% (200 tests<br>system) | 99.87% (manual<br>method)<br>99.97% (Biotis<br>system) | Bio-Rad Laboratories, Stemwilde,<br>France                               | HIV-1 p24 antigen and<br>HIV-2 antibodies            | 15 months<br>2 to 8°C                               | Serum and plasma specimens.<br>For product use: serum (500 test), with solution (10 test)<br>and stopping solution (35 test) must be ordered separately.<br>Reagents designed for use:<br>For venipuncture use: plasma specimen:<br>Venipuncture or capillary and blood collection tubes:<br>Tubes, pipette (and 500), EIA plate washer, EIA plate<br>reader, EIA plate reader, venous dilution system,<br>measuring optodes, (reagent bridge), controlled or distilled<br>water, 100% HIV Control AG/AB EIA is approved for use<br>with the Bio-Rad EVID <sup>TM</sup> Automated Microplate System. | CE mark (PMA)                                                                             |
|                                             |                                           | 960                        |                                                       |                                                        |                                                                          |                                                      |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
| IVCOMB CE                                   | HIV Ab & Ag EIA                           | 392                        | 100.00%                                               | 99.50%                                                 | DIA, PHD Diagnostics Bioprobes S.r.l.<br>Italy                           | HIV-1/2 antibodies and HIV-1<br>p24 antigen          | 15 months<br>2 to 8°C                               | Serum or plasma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CE mark                                                                                   |
|                                             |                                           | 96                         | 100.00%                                               | 99.50%                                                 |                                                                          |                                                      |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
| IVCOMB CE 180                               | HIV Ab & Ag EIA                           | 480                        | 100.00%                                               | 99.50%                                                 | DIA, PHD Diagnostics Bioprobes S.r.l.<br>Italy                           | HIV-1/2 antibodies and HIV-1<br>p24 antigen          | 15 months<br>2 to 8°C                               | Serum or plasma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CE mark                                                                                   |
| IVCOMB CE 560                               |                                           | 960                        | 100.00%                                               | 99.50%                                                 |                                                                          |                                                      |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                           |
| 201375                                      | HIV 1&2 Ag, cut-off                       | 1896                       | 100.00%                                               | 99.82%                                                 | Dialab GmbH,<br>Austria                                                  | HIV-1/2 antibodies                                   | 15 months<br>2 to 8°C                               | Serum or plasma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CE mark                                                                                   |
| 201303                                      | HIV 1&2 Ag, cut-off                       | 396                        | 100.00%                                               | 99.92%                                                 | Dialab GmbH,<br>Austria                                                  | HIV-1/2 antibodies                                   | 15 months<br>2 to 8°C                               | Serum or plasma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CE mark                                                                                   |

# **HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays (CIAs))** (not intended to be used as a donor screening test – unless otherwise specified)

\* (new) marks in WHO prequalified list

| Manufacturer Product Catalogue number | Product Name                                        | Number of tests per kit | Total Sensitivity | Total Specificity | Manufacturer                      | Analysite                                                              | Archived at 25°C Sensitivity/ Specificity (months) | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Regulatory WHO or EMEA number                      |
|---------------------------------------|-----------------------------------------------------|-------------------------|-------------------|-------------------|-----------------------------------|------------------------------------------------------------------------|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| 25438u<br>ZL338u                      | HIV 1&2 Ag/Ab,<br>Double Antibody Sandwich, Truncal | 1x30                    | 100.00%           | 99.95%            | Diatech GmbH,<br>Austria          | HIV-1/2 antibodies and HIV-1 p24 antigen                               | 12 months<br>2-8°C                                 | <p><b>Serum or Plasma</b></p> <p>In ELISA, VICTORIA Plasma specimen</p> <ol style="list-style-type: none"> <li>1. Dispensation (to 96 to 200 µl) of sample</li> <li>2. Positively directed or high quality directed source</li> <li>3. Microplates and Multi-channel interpretation of appropriate volume</li> <li>4. Incubator capable of maintaining the temperature for the defined in the assay protocol</li> <li>5. Modified Heating Block (Code 5500 01) for use in laboratory incubators</li> <li>6. Temperature control</li> <li>7. Automated reference pipette</li> <li>8. Microplate reader</li> </ol> <p>or</p> <ol style="list-style-type: none"> <li>1. Fully automated microplate processor</li> <li>2. All instruments must be validated before use</li> <li>3. Disposable Reaction Trays (Code 3500 01)</li> <li>4. Sodium hypochlorite for decontamination (refer to health and safety information)</li> <li>5. Sodium hydroxide solution (0.1M) for instrument decontamination</li> </ol> | GHIT (CE mark)                                     |
| 9525 01                               |                                                     | 95                      |                   |                   |                                   |                                                                        |                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                    |
| 9525 02                               | Murex HIV-1.2.0                                     | 450                     | 100%              | 99.91%            | Diasorin, Partofa, United Kingdom | HIV-1/2 Antibodies (IgG, IgM, IgA)                                     | 18 months<br>2 to 8°C                              | <p><b>Serum or Plasma</b></p> <ol style="list-style-type: none"> <li>1. Dispensation (to 50 to 200 µl) of sample</li> <li>2. Positively directed or high quality directed source</li> <li>3. Microplates and Multi-channel interpretation of appropriate volume</li> <li>4. Incubator capable of maintaining the temperature for the defined in the assay protocol</li> <li>5. Modified Heating Block (Code 5500 01) for use in laboratory incubators</li> <li>6. Temperature control</li> <li>7. Automated reference pipette</li> <li>8. Microplate reader</li> </ol> <p>or</p> <ol style="list-style-type: none"> <li>1. Fully automated microplate processor</li> <li>2. All instruments must be validated before use</li> <li>3. Disposable Reaction Trays (Code 3500 01)</li> <li>4. Sodium hypochlorite for decontamination (refer to health and safety information)</li> <li>5. Sodium hydroxide solution (0.1M) for instrument decontamination</li> </ol>                                           | GHIT (CE mark, TGA)                                |
| 7575 09 *                             |                                                     | 95                      |                   |                   |                                   |                                                                        |                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                    |
| 7575 11 *                             | Murex HIV Ag/Ab Combination                         | 480                     | 100%              | 99.98%            | Diasorin, Partofa, United Kingdom | Combined Detection of HIV-1 p24 and HIV-1/2 Antibodies (IgG, IgM, IgA) | 12 months<br>2 to 8°C                              | <p><b>Serum or Plasma</b></p> <ol style="list-style-type: none"> <li>1. Dispensation (to 50 to 200 µl) of sample</li> <li>2. Positively directed or high quality directed source</li> <li>3. Microplates and Multi-channel interpretation of appropriate volume</li> <li>4. Incubator capable of maintaining the temperature for the defined in the assay protocol</li> <li>5. Modified Heating Block (Code 5500 01) for use in laboratory incubators</li> <li>6. Temperature control</li> <li>7. Automated reference pipette</li> <li>8. Microplate reader</li> </ol> <p>or</p> <ol style="list-style-type: none"> <li>1. Fully automated microplate processor</li> <li>2. All instruments must be validated before use</li> <li>3. Disposable Reaction Trays (Code 3500 01)</li> <li>4. Sodium hypochlorite for decontamination (refer to health and safety information)</li> <li>5. Sodium hydroxide solution (0.1M) for instrument decontamination</li> </ol>                                           | <p>WHO prequalified</p> <p>GHIT (CE mark, TGA)</p> |

# HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays (CIAs)) (not intended to be used as a donor screening test - unless otherwise specified)

\* (not) suitable for VITRO prequalified

| Manufacturer Product Catalogue number             | Product Name                                            | Number of tests per kit | Initial sensitivity | Final sensitivity                                               | Manufacturer                                        | Analyte                                                                                          | Antibody shelf life (months) after opening | Comments                                                                                                                                                                                                                                                                                        | Eligibility VED or CTR countries |
|---------------------------------------------------|---------------------------------------------------------|-------------------------|---------------------|-----------------------------------------------------------------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| 310850                                            | ELISON XL                                               | 200                     | 100%                | 99.90%                                                          | Diagnostica S.p.A., Saluggia (Vercelli, Italy)      | HIV-1 p24 antigen and HIV-1/2 antibodies                                                         | 12 months at 2 to 8°C                      | serum or plasma specimens                                                                                                                                                                                                                                                                       | GHIT/CE mark, TGA                |
| 80163                                             | INNOTEST HIV Ag mab                                     | 98                      | 100%                | 100.00%                                                         | Pyloridin Gruppe N.V., Ghent, Belgium               | p24 core antigen of the human immunodeficiency virus type 1 (HIV-1), group O, and type 2 (HIV-2) |                                            | human serum, plasma, or cell culture supernatant                                                                                                                                                                                                                                                | GHIT/CE mark                     |
| 80164                                             |                                                         | 480                     |                     |                                                                 |                                                     |                                                                                                  |                                            |                                                                                                                                                                                                                                                                                                 |                                  |
| 684 2751                                          | VITROS Immunodiagnostic Products HIV Combo Reagent Pack | 100                     | 100%                | 98.5%                                                           | Ortho-Clinical Diagnostics, Rariden, United Kingdom | Combined detection of HIV-1 p24 and HIV 1/2 antibodies                                           | short life in refrigerator at 2 to 8°C     | Note: The VITROS HIV Combo Reagent Pack is not intended for use in screening blood or plasma donors. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening assays are unavailable or their use is impractical. | GHIT/CE mark, PMA                |
| (05 390 095 190) being replaced by 08 924 115 190 | Eliscay HIV Combi PT                                    | 300                     | 100%                | 99.82% (blood donor specimens)<br>99.8% (diagnostic specimens)  | Roche Diagnostics, Mannheim, Germany                | HIV 1 p24 antigen and HIV 1/2 antibodies                                                         | 15 months at 2 to 8°C (Do not freeze)      | Serum and plasma specimens<br>coba s 421 antibody, cobra s 401 / 621 modules<br>Note: Specimens collected from living patients, blood donors, or individuals or plasma, serum or cell donors may be used, including donor samples obtained within the donor's heart in all testing.             | GHIT/CE mark                     |
| (07 914 504 190) being replaced by 08 924 115 190 |                                                         | 300                     |                     |                                                                 |                                                     |                                                                                                  |                                            |                                                                                                                                                                                                                                                                                                 |                                  |
| (07 229 315 190) being replaced by 08 836 973 190 | Phosor® HIV Duo                                         | 300                     | 100%                | 99.87% (blood donor specimens)<br>99.92% (diagnostic specimens) | Roche Diagnostics, Mannheim, Germany                | HIV 1 p24 antigen and HIV 1/2 antibodies                                                         | 18 months at 2 to 8°C (Do not freeze)      | Serum and plasma specimens<br>coba s 402 antibody, cobra s 401 / 621 modules<br>Note: Specimens collected from living patients, blood donors, or cell donors may be used, including donor samples obtained within the donor's heart in all testing.                                             | GHIT/CE mark                     |

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays) (CIAI) (not intended to be used as a donor screening test) – unless otherwise specified)

\* (star) mark is WHO prequalified product codes superscripted with a

[illegible]

N/A- NOT AFFILIABLE

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