National GENETICS INSTITUTE
LabCorp Specialty Testing Group

Performance of the NGI UltraQual® Multiplex Assay

The new innovative assay from NGI, enables simultaneous and sensitive detections of four viral targets in a single sample. The tables below provide comparative data for general assay characteristics, sensitivities, and specific genotype detection.

General Characteristics

This table compares the general characteristics of the assays.

Assay	Viruses Detected	Maximum Approved Source Plasma Pool Size	Discriminates between Viruses	Dual Target for HIV-1
UltraQual® Multiplex	HCV, HBV, HIV 2, HIV-1 (Gr M and O)[1]	512[1]	Yes[1,a]	Yes*
cobas® TaqScreen MPX, v2.0	HCV, HBV, HIV-2, HIV-1 (Gr M and O)[2]	96[2]	Yes[2,b]	No[2]
Procleix® Ultrio Plus®	HCV, HBV, HIV-1 (Gr M and O)[3]	16[3]	No[3]	Yes[4]
Procleix® Ultrio Elite®	HCV, HBV, HIV-2, HIV-1 (Gr M and O)[5]	96[5]	No[5]	Yes[4]

a Does not discriminate between HIV-1 Group M and Group O
b Does not discriminate between HIV-1 Group M, HIV-1 Group O, and HIV-2

Analytical Sensitivities

Assay target virus analytical sensitivities and the corresponding 95% confidence intervals are compared in this table.

	Average 95% Limit of Detection (95% Confidence Intervals) IU/mL				
Assay	HCV	HIV-1 Gr M	HIV-1 Gr O[c]	HIV-2	HBV
UltraQual® Multiplex*	1.7 (1.4 – 2.4)	10.0 (8.3 – 12.9)	5.6 (4.7 – 7.1)	3.0 (2.5 – 4.1)	0.7 (0.5 – 0.9)
cobas® TaqScreen MPX, v2.0	6.8 (5.8 – 8.3)	46.2 (35.5 – 65.9)	18.3 (13.1 – 30.9)	7.9 (5.6 – 13.8)	2.3 (2.0 – 2.8)
Procleix® Ultrio Plus[3]	5.4 (4.5 – 6.7)	21.2 (18.2 – 25.7)	Not Determined	Not Detected	3.4 (3.0 – 4.1)
Procleix® Ultrio Elite[5]	3.0 (2.5 – 3.9)	18.0 (15.0 – 23.5)	Not Determined	10.4 (8.9 – 12.6)	4.3 (3.8 – 5.0)

c Copy/mL

Genotype/Subtype Detection

The target genotypes/subtypes shown to be detected by each assay are listed in this table. Other genotypes/subtypes may be detected by these assays but at this point have not been demonstrated.

Assay	HCV	HIV-1	HIV-2	HBV
UltraQual® Multiplex*	1/1a, 1a, 1b, 1, 2a, 2b, 3, 3a, 3b, 4, 4/4a, 4a, 5, 5a, 6, 6a	Group M: A, A1, B, C, D, F, F1, G, H, J, K, CRF03, CRF01, CRF02, CRF02/G, CRF01/CRF15, K/CRF09, B/D, CRF12, D/K, B/C, HA/1, Group N, and Group O	A and B	A-H
cobas® TaqScreen MPX, v2.0[2]	1a, 1b, 2, 2a, 2b, 3a, 4, 4a, 4acd, 4d, 5a, 6, 6ab, 6c	Group M: A, B, C, D, E, F, G, J, AE, AG, G-BG, Group N , and Group O	A and B	A-F
Procleix® Ultrio Plus[3]	1-6	Group M: A, B, C, D, E, F, G and H, Group N , and Group O	Not Applicable	A-G
Procleix® Ultrio Elite[5]	1-6	Group M: A, B, C, D, E, F, G, H, K, AE, AG, and AB, Group N, and Group O	A and B	A-H

*Derived from internal data.

References
1. U.S Food & Drug Administration. NGI UltraQual Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV. https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm609352.htm. Accessed June 2, 2018.
2. cobas® TaqScreen MPX Test, version 2.0 [package insert]. Indianapolis, IN: Roche Diagnostics; 2014.
3. Procleix® Ultrio Plus® [package insert]. San Diego, CA: Novartis Diagnostics; 2012.
4. GenomeWeb. Q&A: New Novartis Dx President Discusses Nucleic Acids Testing, Blood Screening Business. GenomeWeb. March 15, 2012. https://www.genomeweb.com/pcrsample-prep/qa-new-novartis-dx-president-discusses-nucleic-acid-testing-blood-screening-busi#.Wx6-d9VKiCg. Accessed October 14, 2013.
5. Procleix® Ultrio Elite Assay [package insert]. Emeryville, CA: Grifolis Diagnostics; 2017.