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PUBLICATION SUMMARY

CLINICAL PERFORMANCE OF ALINITY M HIV ASSAY (CE)

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MULTICENTER CLINICAL EVALUATION OF ALINITY M HIV-1 ASSAY PERFORMANCE

Authors: Patrick Braun[a], Allison Glass[b], Leana Maree[b], Maria Krügel[b], Monia Pacenti[c], Francesco Onelia[c], Rory Gunson[d], Emily Goldstein[d], Laura Martínez García[e], Juan-Carlos Galán[e], Alba Vilas[f], Jodie D'costa[g], Rizmina Sameer[g], Robert Ehret[a], Heribert Knechten[a], Gudrun Naeth[a], Magali Bouvier-Alias[h], Natalia Marlowe[i], Michael J. Palm[i], Ajith M. Joseph[i], Jens Dhein[j], Birgit Reinhardt[j], Karin Pfeifer[j], Danijela Lucic[i], Martin Obermeier[k]

BACKGROUND It has been estimated that there are 37.9 million individuals living with HIV-1 worldwide, with 24.5 million receiving antiretroviral treatments. The Joint United Nations Program on HIV/AIDS (UNAIDS) organization announced the 90-90-90 program which aims to close the gap between HIV-1 diagnosis, treatment and viral suppression. In order to address the goals of this program, early diagnosis and accurate HIV-1 RNA viral load monitoring is critical. This paper details the findings of an international multicenter study comparing performance of the Alinity m HIV-1 Assay to four commercially available HIV-1 viral load assays.

METHODS Surplus patient plasma (n=2238) specimens from patients with HIV-1 infection were analyzed at nine international laboratories from Europe, Africa and Australia. Comparator assays were RealTime HIV-1 assay (Abbott), CAP/CTM HIV-1 v2.0 assay (Roche), Versant kPCR 1.5 assay (Siemens) or Aptima HIV-1 Quant assay (Hologic).

RESULTS Performance of the Alinity m HIV-1 Assay was comparable to that of several HIV-1 assays widely used in clinical practice. An excellent correlation (correlation coefficients ≥0.955) was observed between the Alinity m HIV-1 assay and the four comparator HIV-1 viral load assays with an overall bias ranging from -0.1 to 0.1 Log_{10} copies/mL. The differences between Alinity m HIV-1 and any comparator assay was ≤1 Log_{10} copies/mL for 98.5% of quantifiable clinical samples. A high level of agreement was observed at the clinical decision points of 200 and 50 copies/mL, in addition to a high level of detectability (≥97%) and reproducibility across the study sites. Subtype information was available for a subset of samples (n=100) covering 16 subtypes. Alinity m HIV-1 demonstrated comparable detection to the RealTime HIV-1 assay for these 16 subtypes (R^2 = 0.956).

CONCLUSION The Alinity m HIV-1 Assay (CE) offers comparable performance against four commercially available HIV-1 viral load assays used in multiple independent study sites and across a wide range of HIV-1 subtypes. As Alinity m is a fully automated, continuous and random access molecular diagnostic analyzer, there is the potential to enable same day reporting of HIV-1 test results and shorten the time between diagnosis and treatment, which may improve patient management.

- Clinical comparison demonstrated high degree of correlation (correlation coefficients ≥0.955) and low bias (-0.1 t o 0.1 Log_{10} copies/mL) when compared with 4 HIV-1 viral load assays in an international multicenter study
- High level of agreement at clinical decision points (200 and 50 copies/mL) against 4 HIV-1 assays providing confidence for patient management
- Alinity m eliminates batching and provides fully automated, continuous, and random access enabling same day results

Reference: Braun P, Glass A, Maree L, Krűgel M, Pacenti M, Onelia F, Gunson R, Goldstein E, , García LM, Galán J-Carlos, Vilas A, D'costa J, Sameer R, Ehret R, Knechten H, Naeth G, Bouvier-Alias M, Marlowe N, Palm MJ, Joseph AM, Dhein J, Reinhardt B, Pfeifer K, Lucic D, Obermeier M, Multicenter Clinical Comparative Evaluation of Alinity m HIV-1 Assay Performance, Journal of Clinical Virology (2020), doi: https://doi.org/10.1016/j.jcv.2020.104530

a Laboratory Dr. Knechten, Medical Center for HIV and Hepatitis, Aachen, Germany; b Lancet Laboratories, Johannesburg, South Africa; c Azienda Ospedaliera di Padova, Padua, Italy; d West of Scotland Specialist Virology Center, Glasgow, United Kingdom; e Servicio de Microbiología. Hospital Universitario Ramón y Cajal and Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS) and CIBER en Epidemiología y Salud Pública (CIBERESP), Madrid, Spain; f Laboratori de Referència de Catalunya, El Prat de Llobregat, Spain; g Victorian Infectious Diseases Reference Laboratory, Royal Melbourne Hospital, at the Peter Doherty Institute for Infection and Immunity, Victoria, 3000, Australia; h Hôpital Henri Mondor, Université Paris-Est, Créteil, France; I Abbott Molecular Inc. Des Plaines, IL, USA; j Abbott GmbH, Wiesbaden, Germa-ny; k Medizinisches Infektiologiezentrum Berlin, Germany

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