Abbott

PUBLICATION SUMMARY

CLINICAL PERFORMANCE OF ALINITY M HCV ASSAY (CE)

CLICK OR SCAN TO ACCESS THE COMPLETE PAPER ONLINE

MULTICENTER CLINICAL EVALUATION OF ALINITY M HCV ASSAY PERFORMANCE

Authors: Stéphane Chevaliez[a,b], Francesco Onelia[c], Monia Pacenti[d], Emily Goldstein[e], Juan-Carlos Galán[f], Laura Martínez-García[f], Alba Vilas[g], Allison Glass[h], Leana Maree[h], Maria Krügel[h], Robert Ehret[i], Heribert Knechten[j], Patrick Braun[j], Gudrun Naeth[j], Sara Bonanzinga[k], Kathy Jackson[k], Klara Abravaya[l], Jens Dhein[m], Shihai Huang[l], Ajith M. Joseph[l], Danijela Lucic[l], Natalia Marlowe[l], Michael J. Palm[l], Karin Pfeifer[m], Dan Toolsie[l], Birgit Reinhardt[m], Martin Obermeier[i], Rory Gunson[e]

BACKGROUND There are an estimated 71 million people worldwide living with chronic HCV infection and nearly 600,000 people die annually from complications associated with HCV infection, such as cirrhosis and hepatocellular carcinoma. Even with the recent availability of highly effective direct acting antivirals, HCV infection remains a global health concern. Accurate and sensitive assays are recommended by international clinical practice guidelines for therapy initiation as well as for cure assessment (Sustained Virologic Response (SVR) 12 or 24). This paper details the findings of an international multicenter study comparing performance of the Alinity m HCV Assay to three commercially available HCV viral load assays.

METHODS Residual serum (n=406) and plasma (n=1401) specimens from patients with chronic HCV infection were analyzed at nine international laboratories from Europe, Africa and Australia. Comparator assays were RealTime HCV assay (Abbott), cobas HCV on cobas 6800 (Roche), or Aptima HCV QuantDx assay (Hologic).

- International multicenter study with 9 study sites
- Accurate quantitation and rapid detection of HCV which may improve patient care and outcomes
- Alinity m eliminates batching and provides fully automated, continuous, and random access enabling same day results
- Analytical performance was confirmed by accurate quantification across the HCV genotypes 1-6, excellent linearity, sensitivity, precision and reproducibility when compared to 3 HCV viral load assays

RESULTS Performance of the Alinity m HCV Assay was comparable to that of several HCV viral load assays widely used in clinical practice. The study demonstrated that Alinity m HCV had excellent correlation (correlation coefficients ≥0.96) with low overall bias (-0.01 to 0.14 Log_{10} IU/mL) when compared with the three comparator HCV viral load. The Alinity m HCV Assay demonstrated linear quantification of HCV RNA in serum with a correlation coefficient of r = 1.00. Genotype information was available for a subset of serum samples (n=375) and a strong relationship was observed between HCV RNA levels measured in the same sample using Alinity m HCV and RealTime HCV for genotypes 1 to 6.

CONCLUSION The Alinity m HCV Assay (CE) is sensitive, reproducible and accurately quantifies HCV RNA in serum and plasma samples. The authors suggest that there would most likely be no implication for clinical practice due to the observed low differences in performance between Alinity m HCV and the other three assays in this study. Quantification is linear across the full dynamic range of the assay and covers values observed in untreated and DAA-treated patients. As Alinity m is a fully automated, continuous and random access molecular diagnostic analyzer, there is the potential to enable same day reporting of HCV test results and shorten the time between diagnosis and treatment, which may improve patient management.

Reference: Chevaliez S, Onelia F, Pacenti M, Goldstein E, Galán J-Carlos, Martínez García L, Vilas A, Glass A, Maree L, Krügel M, Ehret R, Knechten H, Braun P, Naeth G, Bonanzinga S, Jackson K, Abravaya K, Dhein J, Huang S, Joseph AM, Lucic D, Marlowe N, Palm MJ, Pfeifer K, Toolsie D, Reinhardt B, Obermeier M, Gunson R, Multicenter Clinical Evaluation of Alinity m HCV Assay Performance, Journal of Clinical Virology (2020), doi: https://doi.org/10.1016/j.jcv.2020.104531

a National Reference Center for Viral Hepatitis B, C, and D, Department of Virology, Hôpital Henri Mondor, Université Paris-Est, Créteil, France; b INSERM U955, Créteil, France; c Università di Padova, Padua, Italy; d Azienda Ospedaliera di Padova, Padua, Italy; e West of Scotland Specialist Virology Centre, Glasgow, UK; f 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; g Laboratori de Referència de Catalunya, El Prat de Llobregat, Spain; h Lancet Laboratories, Johannesburg, South Africa; I Medizinisches Infektiologiezentrum Berlin, Germany; j Laboratory Dr. Knechten, Medical Center for HIV and Hepatitis, Aachen, Germany; k Victorian Infectious Diseases Reference Laboratory, Royal Melbourne Hospital, at the Peter Doherty Institute for Infection and Immunity, Victoria, 3000, Australia; l Abbott Molecular, Des Plaines, IL, USA; m Abbott GmbH, Wiesbaden, Germany

AMD.15240 10/2020