28.01.2022
Center for Centralized Public Procurement in Health
Republic of Moldova

Re: Tender no. ocds-b3wdp1-MD-1636102483031; request Rg02-181 dated 26.01.2022

Dear Sirs

Herewith, we Roche Diagnostics express our respect and thankfulness for your interest in Roche's high-quality diagnostic equipment in the blood safety area.

Following your request, Roche confirms that the cobas® TaqScreen MPX v 2.0 (CE-IVD) [kit 05969492190] and the cobas® TaqScreen MPX v 2.0 (US-IVD) [kit 05969484190] for use with cobas s201 **contain identical reagent formulations; there are no parameter differences between the results algorithms for HBV targets.**

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Date: 2022.02.17 13:47:25 EET
Reason: MoldSign Signature
Location: Moldova

IFUs (Instructions For Use) of the cobas® TaqScreen MPX v 2.0 (CE-IVD) [kit 05969492190] and of the cobas® TaqScreen MPX v 2.0 (US-IVD) [kit 05969484190] may contain different study parameters, e.g. for HBV genotypes inclusivity, due to the different regulatory requirements of different jurisdictions:

- The US FDA requests a different registration study with alternative dilution series;
- Only the data requested by US FDA are shown in the US-IVD IFU, while only the studies requested by EU (CE-IVD) are presented in the CE-IVD IFU

Thus, we confirm that both IFUs, kit 05969492190 (CE-IVD) and kit 05969484190 (US-IVD), identically reflect the clinical and analytical value of the cobas® TaqScreen MPX v 2.0 test.

We remain at your disposal for any further clarifications

Kindest regards

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Annexed: . IFUs (Instructions for Use) kits 05969492190 and 05969484190