Nucleic Acid Amplification Platform Investigative Summary Report

Background: In 2022 it was announced that the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument, a staple in many public health laboratories, would be discontinued. To proactively identify a replacement while leveraging lessons learned, a workgroup of subject matter experts (SMEs) from numerous programs at CDC was formed to investigate existing platforms as well as those on the horizon that could serve research, surveillance, and diagnostic needs across public health.

SMEs assessed platforms submitted through a notice to the federal register (7/05/2022) by reviewing instrument specifications and information from the manufacturers on the following evaluation criteria: suitability for research, surveillance, and diagnostic testing, whether the platform has or can obtain FDA clearance, compatibility with 96-well or higher throughput formats, compatibility with existing CDC or public health lab tests and platforms, software with some flexibility for analysis, and with capability for test development of laboratory developed tests. The overall instrument size, associated consumables, required software, and estimated costs were also considered. It is a recommendation of this group that future CDC-developed tests intended for external use be deployed on and/or compatible with more than one testing platform from Group I and/ or Group II below.

Platforms evaluated: CDC received submissions from nine manufacturers for the following platforms:

- Agena® Biosciences MassARAY System
- CFX™ Opus 96 Dx System/CFX™ Opus 384 Dx System
- Cepheid GeneXpert platform
- Hologic PANTHER® systems
- IDEXX PCR Platform Reagents and Tests
- Luminex/DiaSorin Molecular LIASON® MDX instrument
- QIAGEN QIAcuity Digital PCR Platform
- Roche LightCycler 480 system
- ThermoFisher Scientific Applied Biosystems QuantStudio™ 7 Pro Real-Time PCR System
- ThermoFisher Scientific Applied Biosystems QuantStudio™ 5 Dx Real-Time PCR System
- ThermoFisher Scientific Applied Biosystems QuantStudio™ Dx Real-Time PCR Instrument

CDC SMEs met with each of the manufacturers that made a submission to address any outstanding questions after the review process.

Results and Summary: Nucleic acid detection platforms were prioritized into two groups for further investigation that will include evaluation of existing and future assays on these platforms. We recommend that CDC programs select those that best meet their testing needs and consider bridging assays to more than one platform from the list below. Group I – Best suited for broad public health applications. Programs should evaluate Group I platforms for CDC-developed assays intended for deployment to public health partners.

- ThermoFisher Scientific Applied Biosystems QuantStudio™ 5 Dx Real-Time PCR System
- Bio-Rad CFX Opus Real-Time PCR System
- Roche LightCycler PRO

Group II – Suited for specific public health applications. Programs should evaluate Group II platforms for CDC-developed assays intended for use in scenarios where the throughput or scale are expected to exceed the platforms in Group I.

- ThermoFisher Scientific Applied Biosystems QuantStudio™ 7 Pro Real-Time PCR System
- QIAGEN QIAcuity Digital PCR Platform
- Hologic PANTHER® systems