

Nucleic Acid Extraction Platform Investigative Summary Report

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Background: In 2023 CDC assessed and prioritized nucleic acid amplification platforms, resulting in recommendations for future CDC-developed tests. As a compliment to this activity, nucleic acid extraction platforms were assessed for prioritization as well. A workgroup of subject matter experts (SMEs) from across infectious disease programs at CDC investigated existing platforms as well as those on the horizon that could serve research, surveillance, and diagnostic needs across public health. SMEs assessed information provided by the manufactures on each platform by reviewing instrument specifications and against the following evaluation criteria:

- Suitability for research, surveillance, or assay development, and in vitro diagnostic purposes
 - If suitable for diagnostic purposes, it should have Food and Drug Administration (FDA) clearance for diagnostic use or a research platform capable of obtaining FDA clearance
- Capability of scaling up or down, i.e., 24, 48, 96, or 384 well extractions
- Compatibility with diagnostic, surveillance, or characterization tests targeting a variety of pathogens
- Compatibility with nucleic acid detection platforms determined to be best suited for broad public health applications.
- 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:

- bioMérieux EMAG®
- Promega Maxwell® CSC
- Promega Maxwell® CSC 48
- QIAGEN EZ2 Connect MDx
- QIAGEN QIAcube Connect MDx
- QIAGEN QIASymphony SP
- revvity chemagic™ 360
- Tecan DreamPrep® NAP
- ThermoFisher Scientific KingFisher™ Apex
- ThermoFisher Scientific KingFisher™ Apex Dx
- Roche Diagnostics MagNA Pure 96
- Roche Diagnostics MagNA Pure 24
- Roche Diagnostics cobas® x800 system

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 extraction platforms were prioritized into two groups for further investigation that will include evaluation of existing and future assays. 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.

- QIAGEN EZ2 Connect MDx
- QIAGEN QIAcube Connect MDx
- ThermoFisher Scientific KingFisher™ Apex/Apex Dx
- Roche Diagnostics MagNA Pure 96/24

Group II – Well suited for specific public health applications. Programs should evaluate Group II platforms for CDC-developed assays intended for use in scenarios where the platforms in Group I do not sufficiently meet the needs of the program.

- bioMérieux EMAG®
- Promega Maxwell® CSC
- Promega Maxwell® CSC 48
- QIAGEN QIAsymphony SP