

HOTLINE: Effective February 22, 2021

New Test **3002528** **Bacterial Strain Typing by Next Generation Sequencing** **STRAIN NGS**
 Available Now

Methodology: Massively Parallel Sequencing
Performed: Varies; Batch tested every two weeks
Reported: 1-3 weeks

Specimen Required: Collect: Multiple bacterial isolates that are epidemiologically related
Specimen Preparation: Transport individual isolates on agar slants or on swabs in bacterial transport media. Package isolates together in a sealed container.
Storage/Transport Temperature: Room temperature.
Remarks: Contact the Microbiology Laboratory at (800) 242-2787, extension 2576, prior to submission of the isolates. One report will be generated for each batch tested; billing is per isolate. Order one test, using "Infection control, ####" (your ARUP client number) as the patient name. Include a list of isolate identifiers (do not use patient names) on the requisition or as an order note for electronic orders. Identifiers on the requisition must match identifiers on the isolate samples.
Unacceptable Conditions: Mixed cultures or non-viable organisms.
Stability (collection to initiation of testing): Isolate: Ambient: 1 week; Refrigerated: Unacceptable; Frozen: Unacceptable.

Reference Interval: By report

Interpretive Data:

Method

Whole Genome Sequencing (WGS) is performed using Ion Torrent sequencing chemistry. Reference-free pairwise comparisons are performed using short, overlapping sequence matching (kmer) analysis. Relationships are determined by the percent of kmers that match between isolate pairs.

Interpretation

Predicted relatedness is based on the total number of differences between the isolates, applying the thresholds shown in the table. The dendrogram and relationship matrix (see enhanced report) illustrate isolate relatedness. Interpretation of strain relatedness should be performed by an investigator knowledgeable about whole genome strain typing procedures and based on all available epidemiological evidence. Inferred relationships based on any strain typing method should not be used for individual patient management.

WGS Strain Typing provides substantial improvements in resolution and reproducibility when compared to pulsed-field gel electrophoresis (PFGE) and can be performed on a broad range of microorganisms. Test was validated for *Staphylococcus*, *Acinetobacter*, *Enterococcus*, *Escherichia*, *Pseudomonas*, *Stenotrophomonas*, *Serratia*, and *Klebsiella* species.

Category	Kmer Identity	Epidemiological Interpretation
Indistinguishable	≥99.9	Part of the outbreak
Closely related	99.8-99.2	Probably part of the outbreak
Possibly related	99.1-95.0	Possibly part of the outbreak
Unrelated	<95.0	Not part of the outbreak

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Note: Each Isolate billed separately

CPT Code(s): 87153

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.