Overview

Useful For
Identifying carriers of carbapenem-resistant Enterobactericeae harboring KPC (Klebsiella pneumoniae carbapenemase) or NDM (New Delhi metallo-beta-lactamase) genes

Method Name
Real-Time Polymerase Chain Reaction (PCR) using LightCycler and Fluorescent Resonance Energy Transfer (FRET)

NY State Available
Yes

Specimen

Specimen Type
Varies

Advisory Information
This assay should be used for surveillance testing on perirectal/rectal swabs or fecal specimens. If testing isolates from culture, order KPNRP / KPC (blaKPC) and NDM (blaNDM) in Gram-Negative Bacilli, Molecular Detection, PCR, Varies.

Necessary Information
Specimen source is required.

Specimen Required
The high sensitivity of amplification by PCR requires the specimen to be processed in an environment in which contamination of the specimen by KPC or NDM DNA is not likely.

Submit only 1 of the following specimens:

Supplies:
- Culturette (BBL Culture Swab) (T092)
- C and S Vial (T058)

Preferred:
Specimen Type: Perianal, perirectal, rectal

Collection Container/Tube: Culture transport swab (Dacron or rayon swab with aluminum or plastic shaft with either Stuart or Amies liquid medium)

Specimen Volume: Swab

Acceptable:
**Test Definition: KNSRP**

**KPC and NDM Surveillance PCR**

**Specimen Type:** Preserved feces

**Container/Tube:** Commercially available transport system specific for recovery of enteric pathogens from fecal specimens (15 mL of non-nutritive transport medium containing phenol red as a pH indicator, either Cary-Blair or Para-Pak C and S)

**Specimen Volume:** Representative portion of feces

**Forms**

If not ordering electronically, complete, print, and send a **Microbiology Test Request** (T244) with the specimen.

**Specimen Minimum Volume**

See Specimen Required

**Reject Due To**

<table>
<thead>
<tr>
<th>Swab</th>
<th>E-swab, calcium alginate swab, cotton-tipped swab, swab sent in gel transport medium, swab sent in viral or universal transport medium</th>
</tr>
</thead>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>7 days</td>
<td></td>
</tr>
</tbody>
</table>

**Clinical and Interpretive**

**Clinical Information**

The Centers for Disease Control and Prevention recommends active surveillance to detect unrecognized colonized patients who may be a potential source for carbapenem-resistant (drug-resistant) *Enterobacteriaceae* (CRE) transmission. Such surveillance testing may be focused in certain high-risk settings or patient groups (eg, ICUs, long-term acute care, patients transferred from areas or facilities with high CRE prevalence) or by infection control to investigate an outbreak. Nonsusceptibility to carbapenems in gram-negative bacilli by means of the enzyme KPC (*Klebsiella pneumoniae* carbapenemase) or NDM (New Dehli metallo-beta-lactamase) is becoming more common. The genes *bla*KPC and *bla*NDM encode KPC and NDM enzyme production, respectively. PCR is a sensitive, specific, and rapid means identifying patients colonized by CRE harboring *bla*KPC or *bla*NDM.

**Reference Values**

Not applicable

**Interpretation**

This PCR detects and differentiates *bla*KPC and *bla*NDM in surveillance specimens (perirectal/rectal swabs or feces). A positive KPC (*Klebsiella pneumoniae* carbapenemase) and/or NDM (New Dehli metallo-beta-lactamase) PCR result indicates that the patient is colonized by a Gram-negative bacillus (or Gram-negative bacilli) harboring a carbapenemase gene, *bla*KPC and/or *bla*NDM, respectively.

A negative result indicates the absence of detectable DNA.
Cautions
False-negative results may occur due to inhibition of PCR, sequence variability underlying primers and probes, or the presence of the blaKPC or blaNDM genes in quantities lower than the limit of detection of the assay.

Supportive Data
The performance of this assay was demonstrated by spiking perirectal swab and stool specimens (30 positive and 30 negative for each specimen type) with quantified heat-killed bacteria carrying blaNDM or blaKPC. The sensitivity and specificity in spiked stool specimens was 100% for both blaNDM and blaKPC; for perirectal swabs the sensitivity and specificity was 93% and 100%, respectively, for blaKPC and 100% and 100%, respectively, for blaNDM. The assay had the following limits of detection in perirectal swabs and stool, respectively: blaKPC, 9 and 90 CFU/microliter and blaNDM 1.9 and 1.9 CFU/microliter.

In addition, 33 rectal swab specimens previously characterized as containing isolates of KPC PCR-positive Enterobacteriaceae using the method of Lolans(1) were tested by the Mayo Clinic KPC and NDM PCR assay. There was complete agreement with the expected results.

Clinical Reference


3. New carbapenem-resistant Enterobacteriaceae warrant additional action by healthcare providers. Centers for Disease Control and Prevention Health Alert Network, February 14, 2013


Performance

Method Description
Perirectal swabs are processed in neutralization buffer tubes and organisms are lysed to release their genomic material. Stool specimens undergo DNA extraction prior to PCR. This assay amplifies and detects a specific portion of the genes encoding the KPC (Klebsiella pneumoniae carbapenemase) and NDM (New Delhi metallo-beta-lactamase) enzymes. The LightCycler instrument amplifies and monitors target nucleic acid sequences by fluorescence during PCR cycling. This is an automated PCR system that can rapidly detect amplified product development through stringent air-controlled temperature cycling and capillary cuvettes. The detection of amplified products is based on the fluorescent-resonance energy transfer (FRET) principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3’ end is excited by an external light source, which emits light that is absorbed by a second hybridization probe with an acceptor fluorophore LC-Led 610 (blaKPC specific) and LC-red 670 (blaNDM specific), on the 5’ end. The acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product. The detection process is completed in less than 1 hour using a closed tube system. (Cunningham SA, Noorie T, Meunier D, et al: Rapid and simultaneous detection of genes encoding Klebsiella pneumoniae carbapenemase (blaKPC) and New Delhi metallo-beta-lactamase (blaNDM) in Gram-negative bacilli. J Clin Microbiol 2013;51:66-69)
PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
1 day

Maximum Laboratory Time
4 days

Specimen Retention Time
3 days if received in a swab transport

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
87798 x 2

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KNSRP</td>
<td>KPC and NDM Surveillance PCR</td>
<td>85502-3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRCKP</td>
<td>Specimen source</td>
<td>31208-2</td>
</tr>
<tr>
<td>35165</td>
<td>KPC PCR</td>
<td>49617-4</td>
</tr>
<tr>
<td>35166</td>
<td>NDM PCR</td>
<td>73982-1</td>
</tr>
</tbody>
</table>