

GenMark Dx

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Code(s): 0140U, 0141U, 0142U

New Codes 0140U, 0141U, 0142U: Test Purpose and Method

- Test Purpose:
- The GenMark ePlex® Blood Culture Identification Fungal (BCID-FP), Gram-Positive (BCID-GP) and Gram-Negative (BCID-GN) Panels are for the qualitative detection and identification of fungal, gram-positive and gram-negative bacterial organisms and select determinants of antimicrobial resistance in positive blood culture.
- Intended for use as an aid the diagnosis of bloodstream infections when used in conjunction with Gram stain results and other clinical information.
- Test Method:
 - Multiplex nucleic acid amplification
 - Result(s) within 90 minutes
 - ~ 5 minutes technologist hands-on-time

0140U: Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected

Public Comment	Rationale
Gapfill	<ul style="list-style-type: none"><li data-bbox="703 702 2277 903">• No comparable code exists for a panel identifying fungal pathogens that uses an amplified probe technique from a cultured specimen.

0141U: Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected

Public Comment	Rationale
Gapfill	<ul style="list-style-type: none"><li data-bbox="777 696 2295 982">• No comparable code exists for a panel identifying gram-positive organisms and antimicrobial resistance genes that uses an amplified probe technique from a cultured specimen.

0142U: Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected

Public Comment	Rationale
Gapfill	<ul style="list-style-type: none"><li data-bbox="703 698 2308 983">• No comparable code exists for a panel identifying gram-negative organisms and antimicrobial resistance genes that uses an amplified probe technique from a cultured specimen.