



April 2010

TEST UPDATES

www.focusdx.com

This summary of test updates includes details and effective dates for new tests, changes to existing tests, and discontinued tests. For questions or additional information, please contact the Focus Diagnostics Client Services Department at (800) 445-4032. Visit our web site at www.focusdx.com.

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The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Focus Diagnostics requires a current email address to continue to provide updates to our reference laboratory menu. Please inform our Client Services Department if there is a change in staffing or email address.

Call (800) 445-4032 or email ClientServices@focusdx.com.

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NEW TESTS

Antimicrobial Combination Testing, Synergy, 2 Drugs	
Effective Date:	April 12, 2010
Unit Code:	51780
CPT Code(s):	87181 (x4)
List Price:	\$80.00
Specimen Requirements:	Pure isolate, slant or transport swab
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: determined by viability Refrigerated: determined by viability Frozen: unacceptable
Reference Range:	Not applicable
Methodology:	Antibiotic gradient
Set-up Day(s):	Monday – Sunday
Results Available:	3-6 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics, Inc.
	<p>New Test Contact Focus Diagnostics for CPU/Interface mapping. Always message will be:</p> <p>Interpretations of drug combinations (ex: A+B and B+A) are based on the calculated Fractional Inhibitory Concentration (FIC) index that measures the in vitro activity of each primary drug in the presence of each secondary drug. The FIC index is a value obtained from results of both antimicrobial combinations (A in the presence of B and B in the presence of A). The FIC index determines the interpretation such that combinations with:</p> <ol style="list-style-type: none"> 1) An FIC of ≤ 0.5 are reported as "Synergy Detected" indicating the drug combination is significantly more active than each individual drug alone. 2) An FIC of >0.5 to ≤ 1.0 is reported as "Additive" where there is minimal increased activity, not significantly more than the two drugs alone. 3) An FIC of >1.0 to ≤ 4.0 is reported as "Indifference" where there is no increased activity of the combinations. 4) An FIC of >4.0 is reported as "Antagonism detected" indicating drugs actually may work against each other in combination. For a result that indicates Antagonism, the combination therapy is considered to be counter-indicated. <p>If necessary, refer to an appropriate healthcare provider such as an Infectious Disease specialist. Results of in vitro antimicrobial</p>



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	<p>combination testing have not been correlated with clinical efficacy at this time.</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>
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Antimicrobial Combination Test, Synergy, 3 Drugs	
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Effective Date:	April 12, 2010
Unit Code:	5240
CPT Code(s):	87181 (x9)
List Price:	\$180.00
Specimen Requirements:	Pure isolate, slant or transport swab
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: determined by viability Refrigerated: determined by viability Frozen: unacceptable
Reference Range:	Not applicable
Methodology:	Antibiotic gradient
Set-up Day(s):	Monday – Sunday
Results Available:	3-6 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics, Inc.
	<p>New Test</p> <p>This profile consists of:</p> <p>Antimicrobial Combination A+B</p> <p>Antimicrobial Combination A+C</p> <p>Antimicrobial Combination B+C</p> <p>Contact Focus Diagnostics for CPU/Interface mapping.</p> <p>Always message will be:</p> <p>Interpretations of drug combinations (ex: A+B and B+A) are based on the calculated Fractional Inhibitory Concentration (FIC) index that measures the in vitro activity of each primary drug in the presence of each secondary drug. The FIC index is a value obtained from results of both antimicrobial combinations (A in the presence of B and B in the presence of A). The FIC index determines the interpretation such that combinations with:</p> <p>1) An FIC of < or = 0.5 are reported as "Synergy Detected" indicating the drug combination is significantly more active than each individual drug alone.</p> <p>2) An FIC of >0.5 to < or = 1.0 is reported as "Additive" where there is</p>



NEW TESTS

	<p>minimal increased activity, not significantly more than the two drugs alone.</p> <p>3) An FIC of >1.0 to < or = 4.0 is reported as "Indifference" where there is no increased activity of the combinations.</p> <p>4) An FIC of >4.0 is reported as "Antagonism detected" indicating drugs actually may work against each other in combination. For a result that indicates Antagonism, the combination therapy is considered to be counter-indicated.</p> <p>If necessary, refer to an appropriate healthcare provider such as an Infectious Disease specialist. Results of in vitro antimicrobial combination testing have not been correlated with clinical efficacy at this time.</p> <p>This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>
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Antimicrobial Combinations, CF Panel

Effective Date:	April 12, 2010
Unit Code:	5340
CPT Code(s):	87181 (x34)
List Price:	\$675.00
Specimen Requirements:	Pure isolate of <i>Pseudomonas aeruginosa</i> on a slant or transport swab
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: determined by viability Refrigerated: determined by viability Frozen: unacceptable
Reference Range:	Not applicable
Methodology:	Antibiotic gradient
Set-up Day(s):	Monday – Sunday
Results Available:	3-6 days
Assay Category:	Laboratory Developed Test
NYSDOH Approved:	Yes
Performing Site:	Focus Diagnostics, Inc.
	<p>New Test This profile consists of: Piperacillin and Tobramycin Tobramycin and Meropenem Tobramycin and Ceftazidime Tobramycin and Ticar/Clav Tobramycin and Imipenem Tobramycin and Aztreonam</p>

NEW TESTS

**Meropenem and Amikacin
Imipenem and Ciprofloxacin
Ceftazidime and Amikacin
Meropenem and Ciprofloxacin
Piperacillin and Ciprofloxacin
Cefepime and Tobramycin**

Contact Focus Diagnostics for CPU/Interface mapping.

Always message will be:

Interpretations of drug combinations (ex: A+B and B+A) are based on the calculated Fractional Inhibitory Concentration (FIC) index that measures the in vitro activity of each primary drug in the presence of each secondary drug. The FIC index is a value obtained from results of both antimicrobial combinations (A in the presence of B and B in the presence of A). The FIC index determines the interpretation such that combinations with:

- 1) An FIC of ≤ 0.5 are reported as "Synergy Detected" indicating the drug combination is significantly more active than each individual drug alone.**
- 2) An FIC of >0.5 to ≤ 1.0 is reported as "Additive" where there is minimal increased activity, not significantly more than the two drugs alone.**
- 3) An FIC of >1.0 to ≤ 4.0 is reported as "Indifference" where there is no increased activity of the combinations.**
- 4) An FIC of >4.0 is reported as "Antagonism detected" indicating drugs actually may work against each other in combination. For a result that indicates Antagonism, the combination therapy is considered to be counter-indicated.**

If necessary, refer to an appropriate healthcare provider such as an Infectious Disease specialist. Results of in vitro antimicrobial combination testing have not been correlated with clinical efficacy at this time.

This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.



TEST CHANGES

The following section contains updates to existing tests. For complete test information, contact Client Services at 800-445-4032 or visit our website at www.focusdx.com.

<i>Clostridium difficile</i> DNA and Toxin B Gene, Qualitative Real-Time PCR		
Effective Date:	April 12, 2010	
Unit Code:	81435	
CPT Code(s):	87798; 87493	
Additional Information:	Update CPT codes.	
<i>Mycoplasma</i> Comprehensive Culture		
Effective Date:	June 14, 2010	
Unit Code:	51002	
Specimen Requirements:	1 mL Whole blood (sodium heparin green top). Body fluid (in a sterile leak-proof container), CSF, respiratory specimens (M4, UTM, VTM or equivalent), or 3 mm tissue (in M4, UTM, VTM or equivalent).	
Transport Temperature:	Refrigerated preferred; If transporting after 48 hours frozen at <=-70 degrees centigrade	
Specimen Stability:	Room temperature: unacceptable (whole blood 24 hours) Refrigerated: 48 hours (do not refrigerate whole blood) Frozen <=-70 degrees centigrade: 30 days (do not freeze whole blood)	
Reference Range:	None Isolated	
Additional Information:	Update test code title, specimen requirements, transport temperature, specimen stability and reference range.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	5012	<i>Mycoplasma</i> Comprehensive Culture
<i>Campylobacter</i> sp. Antigen, EIA		
Effective Date:	June 14, 2010	
Unit Code:	81330	
Specimen Requirements:	2 mL (0.5 mL min.) or 2 grams (0.5 grams min.) of fresh stool in Cary-Blair transport medium	
Transport Temperature:	Refrigerated	
Specimen Stability:	Room Temperature: Cary-Blair 48 hours Fresh stool unacceptable Refrigerated: 96 hours (all specimens) Frozen: 30 days (all specimens)	
Reference Range:	Not Detected	
Additional Information:	Update reporting title, test code title, specimen requirements, transport temperature, specimen stability and remove always message.	
CPU Interface Mapping:	Test Code (analyte)	Test Code Title
	81330	<i>Campylobacter</i> Antigen



DISCONTINUED TESTS

West Nile Virus IgG Avidity, ELISA	
Effective Date:	June 7, 2010
Unit Code:	42601
Additional Information:	This test will be discontinued. Recommended alternative is: 40428 West Nile Virus Antibody Panel, ELISA

Methicillin Resistant <i>Staphylococcus aureus</i>, PCR	
Effective Date:	June 7, 2010
Unit Code:	47650
Additional Information:	This test will be discontinued. Recommended alternative is: 17656X Methicillin Resistant <i>Staphylococcus aureus</i>, PCR This test is performed at Quest Diagnostics, San Juan Capistrano. Please send directly to Quest Diagnostics, San Juan Capistrano.



Laboratory Director Change

Effective May 1, 2010, Jay M. Lieberman, MD will replace Alfred Lui, MD as Laboratory Director for all states excluding New York State Department of Health. Kenneth Van Horn, PhD will be listed as the Laboratory Director for NYSDOH.

For questions or additional information, please contact the Focus Diagnostics Client Services Department at (800) 445-4032. Visit our web site at www.focusdx.com for a listing of new tests and test updates.