QUIDEL

Cell Culture and Fluorescent Tests

Reimbursement Manual

Contents

Introduction

Thank you for choosing Quidel for your testing needs.

This manual has been developed as a coding reference guide for Quidel cell culture and fluorescent test kits. Please note that all coding scenarios contained herein are specific to those methods included in respective product inserts. As payer reimbursement policies often differ and are subject to change, it is strongly recommended that you consult with each contracted insurance carrier on a regular basis to confirm respective coding, coverage, and payment guidelines prior to submitting claims.

The office of Inspector General (OIG) of the Department of Health and Human Services (HHS) and other Federal agencies have emphasized the importance of voluntarily developed and implemented compliance plans for clinical laboratories, regardless of size. Specific to reimbursement, it is strongly recommended that customers review and implement the medical necessity and billing compliance plan elements developed in the OIG Model Compliance Plan for Clinical Laboratories. This document can be viewed online by visiting:

http://oig.hhs.gov/fraud/docs/complianceguidance/cpcl.html

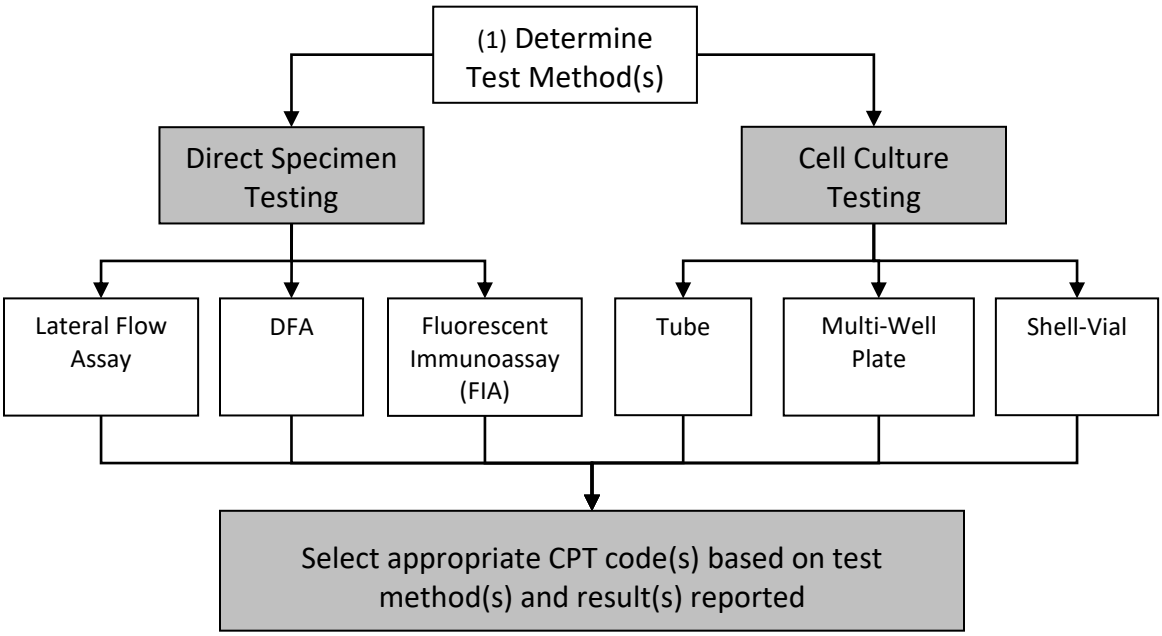
CMS developed the National Correct Coding Initiative (NCCI) and Medically Unlikely Edits (MUEs) to promote national correct coding methodologies and to control improper coding leading to inappropriate payment. Regarding reimbursement for same day testing and/or confirmation testing, it is strongly recommended that customers review and understand these edits, found online at:

http://www.cms.gov/NationalCorrectCodInitEd/

For reimbursement support, please contact CodeMap at 312.291.8408
or e-mail quidel@codemap.com

Respiratory Testing Solutions

Respiratory Testing Coding Roadmap



Respiratory Testing CPT Code Descriptors (Reference)

CPT	Description
87140	Culture, typing; immunofluorescent method, each antiserum
87252	Virus isolation; tissue culture inoculation, observation, and presumptive identification by cytopathic effect
87253	Virus isolation; tissue culture, additional studies or definitive identification (eg, Heme absorption, neutralization, immunofluorescence stain), each isolate
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus
87260	Infectious agent antigen detection by immunofluorescent technique; adenovirus
87275	Infectious agent antigen detection by immunofluorescent technique; influenza B virus
87276	Infectious agent antigen detection by immunofluorescent technique; influenza A virus
87279	Infectious agent antigen detection by immunofluorescent technique; Parainfluenza virus, each type
87280	Infectious agent antigen detection by immunofluorescent technique; respiratory syncytial virus
87299	Infectious agent antigen detection by immunofluorescent technique; not otherwise specified, each organism
87300	Infectious agent antigen detection by immunofluorescent technique, polyvalent for multiple organisms, each polyvalent antiserum
87804	Infectious agent antigen detection by immunoassay with direct optical observation; Influenza
87807	Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus
87880	Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group A

D³® FastPoint® L-DFA Respiratory Virus Identification Kit

Coding for Direct Specimen Testing[1]

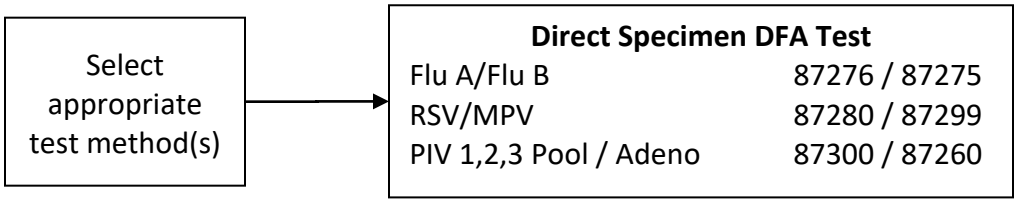
Description	CPT
Influenza A	87276
Influenza B	87275
Respiratory Syncytial Virus (RSV)	87280
Human Metapneumovirus (MPV)	87299
Parainfluenza Pool[2]	87300
Adenovirus	87260

It is recommended that specimens found to be negative for influenza A virus, influenza B virus, RSV, adenovirus, or parainfluenza viruses after examination of the direct specimen result be confirmed by cell culture. Specimens found to be negative for MPV after examination of the direct specimen results should be confirmed by an FDA-cleared human metapneumovirus molecular assay.[3]

Coding for Cell Culture Testing

Appropriate screening and ID kits,[4] as well as cell lines for culture confirmation of negative results may also be purchased from Quidel/Diagnostic Hybrids.

Coding Diagram



[1] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).
[2] Parainfluenza Pool can be typed (PIV 1, PIV 2, PIV 3) using the D³ Ultra™ DFA Parainfluenza Reagent Set.
[3] See product insert.
[4] D³ Ultra DFA Respiratory Virus Screening and ID Kit or the D³ Duet DFA Influenza A/Respiratory Virus Screening Kit.

D^3 FastPoint L-DFA Influenza A/Influenza B Virus Identification Kit

Coding for Direct Specimen Testing[5]

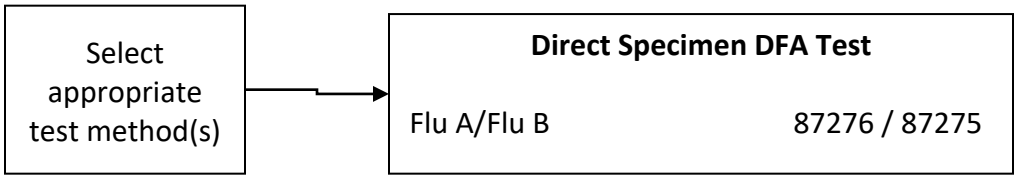
Description	CPT
Influenza A	87276
Influenza B	87275

It is recommended that specimens found to be negative for influenza A or influenza B virus after examination of the direct specimen result be confirmed by cell culture.[6]

Coding for Cell Culture Testing

Appropriate screening and ID kits,[7] as well as cell lines for culture confirmation of negative results may also be purchased from Quidel/Diagnostic Hybrids.

Coding Diagram



[5] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).
[6] See product insert.
[7] D^3 Ultra DFA Respiratory Virus Screening and ID Kit or the D^3 Duet DFA Influenza A/Respiratory Virus Screening Kit.

D[3] FastPoint L-DFA RSV/MPV Identification Kit

Coding for Direct Specimen Testing[8]

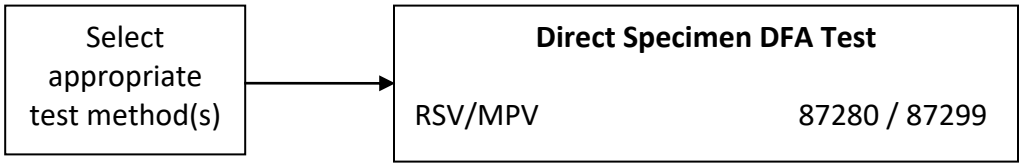
Description	CPT
Respiratory Syncytial Virus (RSV)	87280
Human Metapneumovirus (MPV)	87299

It is recommended that specimens found to be negative for RSV after examination of the direct specimen result be confirmed by cell culture. Specimens found to be negative for MPV after examination of the direct specimen results should be confirmed by an FDA-cleared MPV molecular assay.[9]

Coding for Cell Culture Testing

Appropriate screening and ID kits,[10] as well as cell lines for culture confirmation of negative results may also be purchased from Quidel/Diagnostic Hybrids.

Coding Diagram



[8] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).
[9] See product insert.
[10] D[3] Ultra™ DFA Respiratory Virus Screening and ID Kit or the D[3] Duet™ DFA Influenza A/Respiratory Virus Screening Kit.

D[3] Ultra DFA Respiratory Virus Screening and ID Kit

Coding for Direct Specimen Testing[11]

Description	CPT[12,13]
Respiratory Virus Screen[13]	87300
Influenza A	87276
Influenza B	87275
Respiratory Syncytial Virus (RSV)	87280
Adenovirus	87260
Parainfluenza 1 (PIV 1)	87279
Parainfluenza 2 (PIV 2)	87279-59
Parainfluenza 3 (PIV 3)	87279-59

It is recommended that specimens found to be negative for influenza A virus, influenza B virus, RSV, adenovirus, and parainfluenza viruses after examination of the direct specimen result be confirmed by cell culture.[14]

Coding for Cell Culture[11]

(Alternative to Direct Specimen Testing or for Confirmation of Negatives)

Appropriate cell lines for initial culture testing or for results found to be negative after examination of the direct specimen (DFA or lateral flow test) may also be purchased from Diagnostic Hybrids.

Cell Culture Method	CPT	Modifier (if necessary)[12]
Tube	87252	Not Applicable
Multi-Well Plate	87254	59
Shell-Vial	87254	59

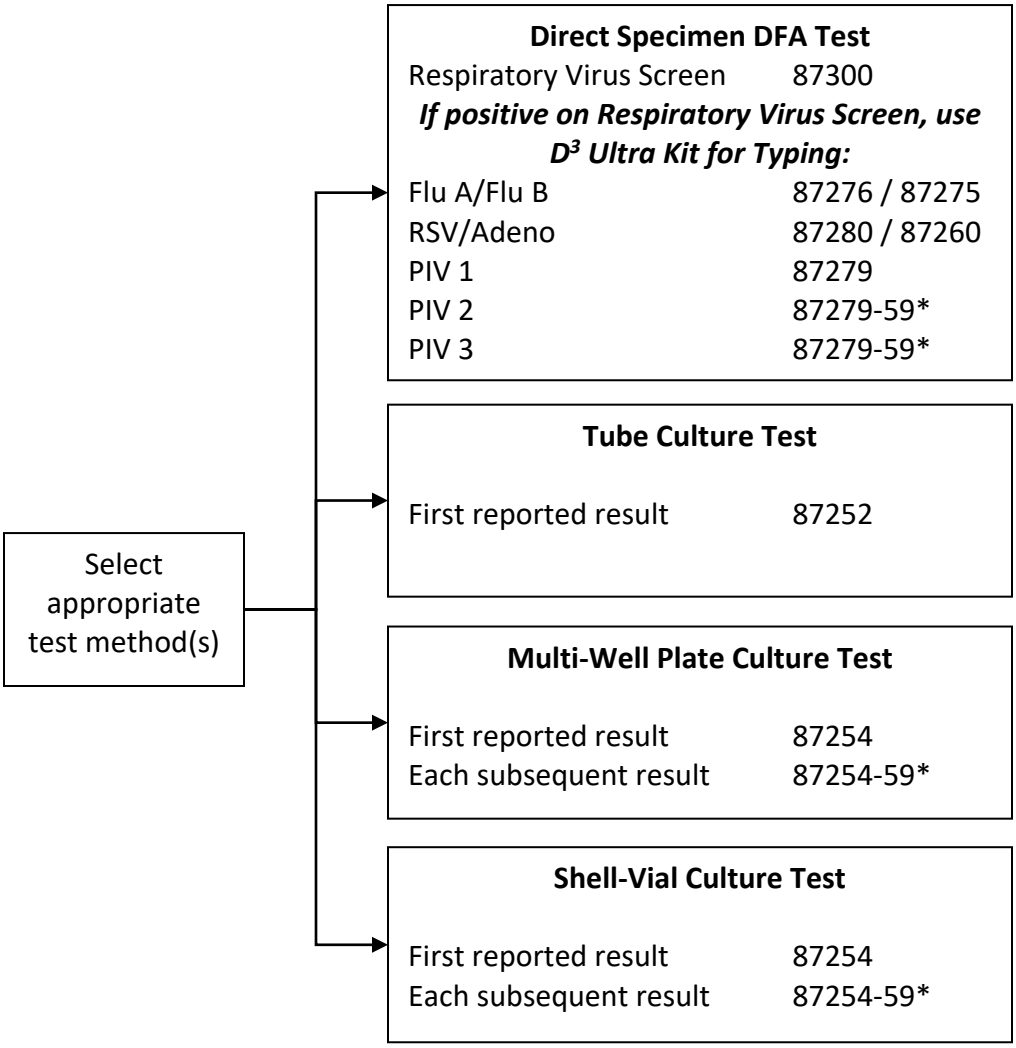
[11] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

[12] For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

[13] Respiratory Virus Screen can by typed (Flu A, Flu B, RSV, Adeno, PIV 1, PIV 2, PIV 3) using the D[3] Ultra DFA Respiratory Virus Screening and ID Kit.

[14] See product insert.

Coding Diagram



* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

D[3] DFA Metapneumovirus Identification Kit

Coding for Direct Specimen Testing[15]

Description	CPT
Human Metapneumovirus (MPV)	87299

Specimens found to be negative for MPV after examination should be confirmed by an FDA-cleared MPV molecular assay.

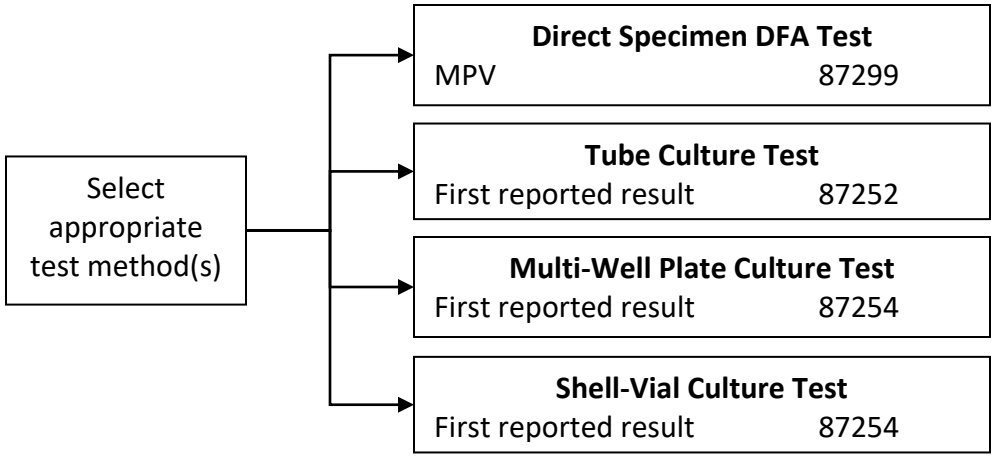
Coding for Cell Culture[15]

(Alternative to Direct Specimen Testing or for Confirmation of Negatives)

Appropriate cell lines for initial culture testing or for results found to be negative after examination of the direct specimen (DFA or lateral flow) may also be purchased from Diagnostic Hybrids.

Cell Culture Method	CPT	Modifier (if necessary)[16]
Tube	87252	Not Applicable
Multi-Well Plate	87254	Not Applicable
Shell-Vial	87254	Not Applicable

Coding Diagram



* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

[15] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

[16] For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

D[3] Duet DFA Influenza A/Respiratory Virus Screening Kit

Coding for Direct Specimen Testing[17]

Description	CPT[18,19]
Influenza A	87276
Respiratory Virus Screen[19]	87300
Influenza B	87275
Respiratory Syncytial Virus (RSV)	87280
Adenovirus	87260
Parainfluenza 1 (PIV 1)	87279
Parainfluenza 2 (PIV 2)	87279-59
Parainfluenza 3 (PIV 3)	87279-59

It is recommended that specimens found to be negative for influenza A virus, influenza B virus, RSV, adenovirus, and parainfluenza viruses after examination of the direct specimen result be confirmed by cell culture.[20]

Coding for Cell Culture[17]

(Alternative to Direct Specimen Testing or for Confirmation of Negatives)

Appropriate cell lines for initial culture testing or for results found to be negative after examination of the direct specimen (DFA or lateral flow) may also be purchased from Diagnostic Hybrids.

Cell Culture Method	CPT	Modifier (if necessary)[18]
Tube	87252	Not Applicable
Multi-Well Plate	87254	59
Shell-Vial	87254	59

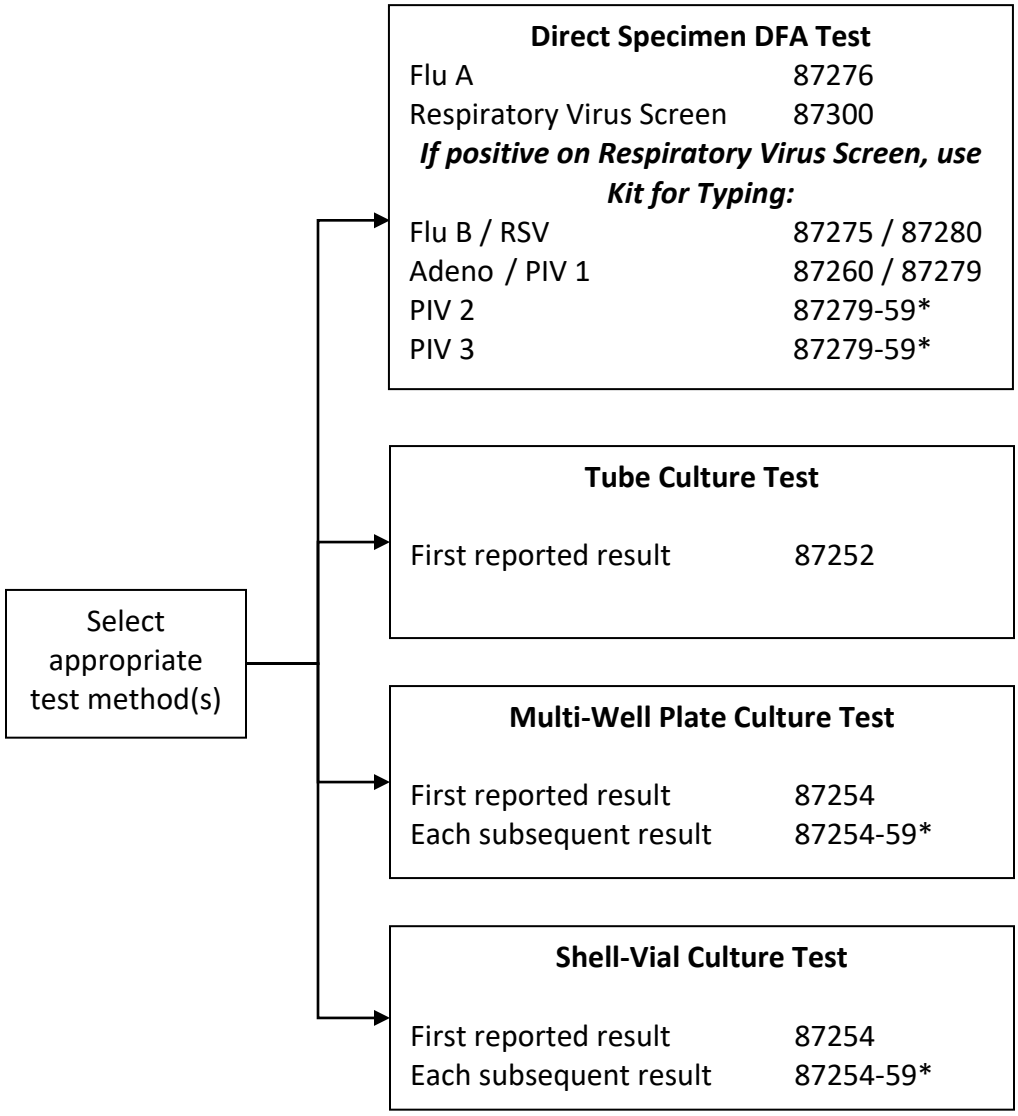
[17] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

[18] For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

[19] Respiratory Virus Screen can by typed (Flu B, RSV, Adeno, PIV 1, PIV 2, PIV 3) using this kit.

[20] See product insert.

Coding Diagram



* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

D[3] Duet DFA RSV/Respiratory Virus Screening Kit

Coding for Direct Specimen Testing[21]

Description	CPT[22,23]
Respiratory Syncytial Virus (RSV)	87280
Respiratory Virus Screen[23]	87300
Influenza A	87276
Influenza B	87275
Adenovirus	87260
Parainfluenza 1 (PIV 1)	87279
Parainfluenza 2 (PIV 2)	87279-59
Parainfluenza 3 (PIV 3)	87279-59

It is recommended that specimens found to be negative for RSV, influenza A virus, influenza B virus, adenovirus, and parainfluenza viruses after examination of the direct specimen result be confirmed by cell culture.[24]

Coding for Cell Culture[21]

(Alternative to Direct Specimen Testing or for Confirmation of Negatives)

Appropriate cell lines for initial culture testing or for results found to be negative after examination of the direct specimen (DFA or lateral flow) may also be purchased from Diagnostic Hybrids.

Cell Culture Method	CPT	Modifier (if necessary)[22]
Tube	87252	Not Applicable
Multi-Well Plate	87254	59
Shell-Vial	87254	59

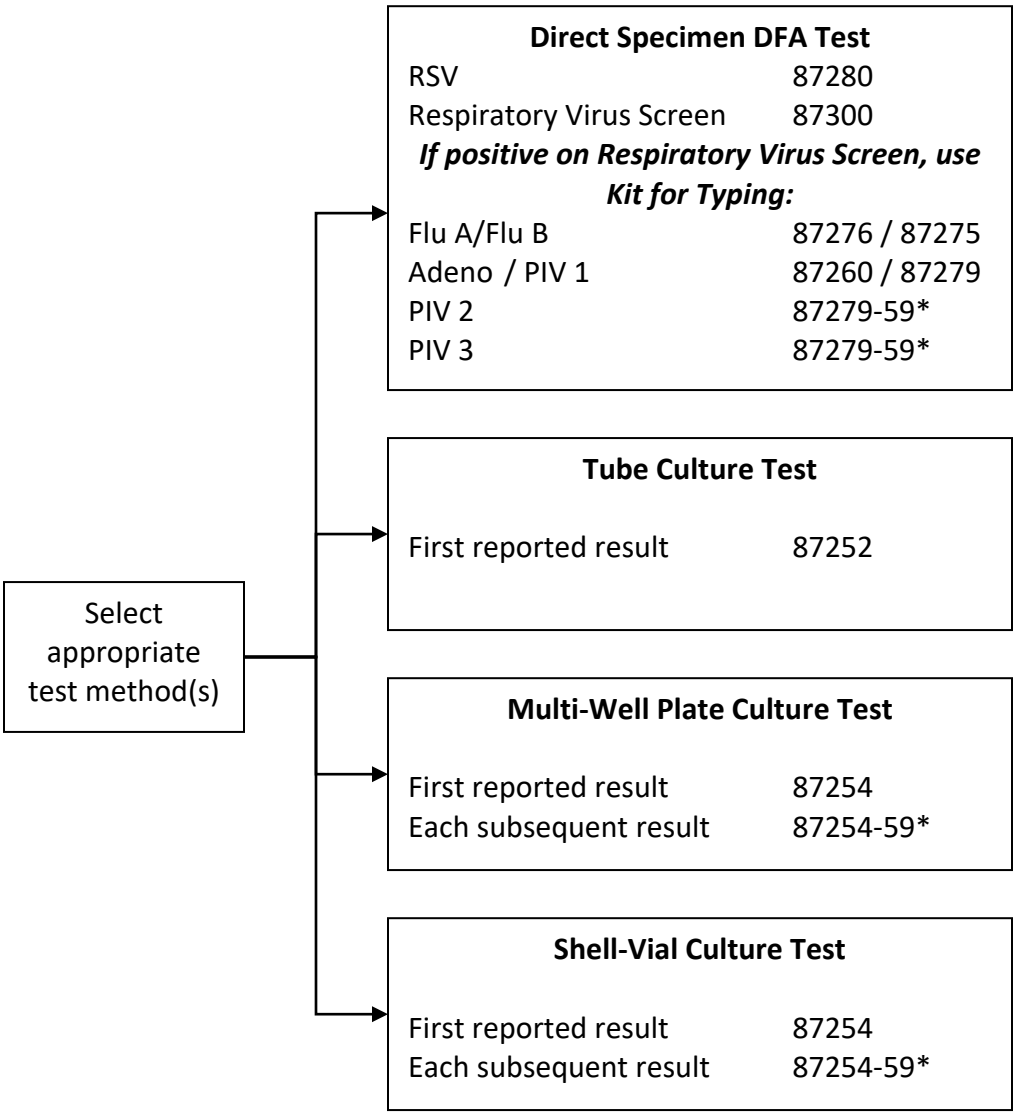
[21] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

[22] For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

[23] Respiratory Virus Screen can by typed (Flu A, Flu B, Adeno, PIV 1, PIV 2, PIV 3) using this kit.

[24] See product insert.

Coding Diagram



* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

Thyroid Testing Solutions

Thyretain® TSI Reporter BioAssay

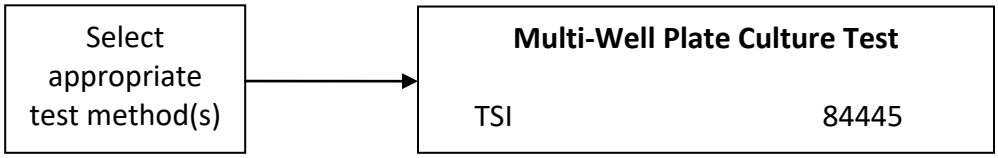
Thyroid Testing CPT Code Descriptor (Reference)

CPT	Description
84445	Thyroid stimulating immune globulins (TSI)

Coding[25]

Description	CPT
TSI	84445

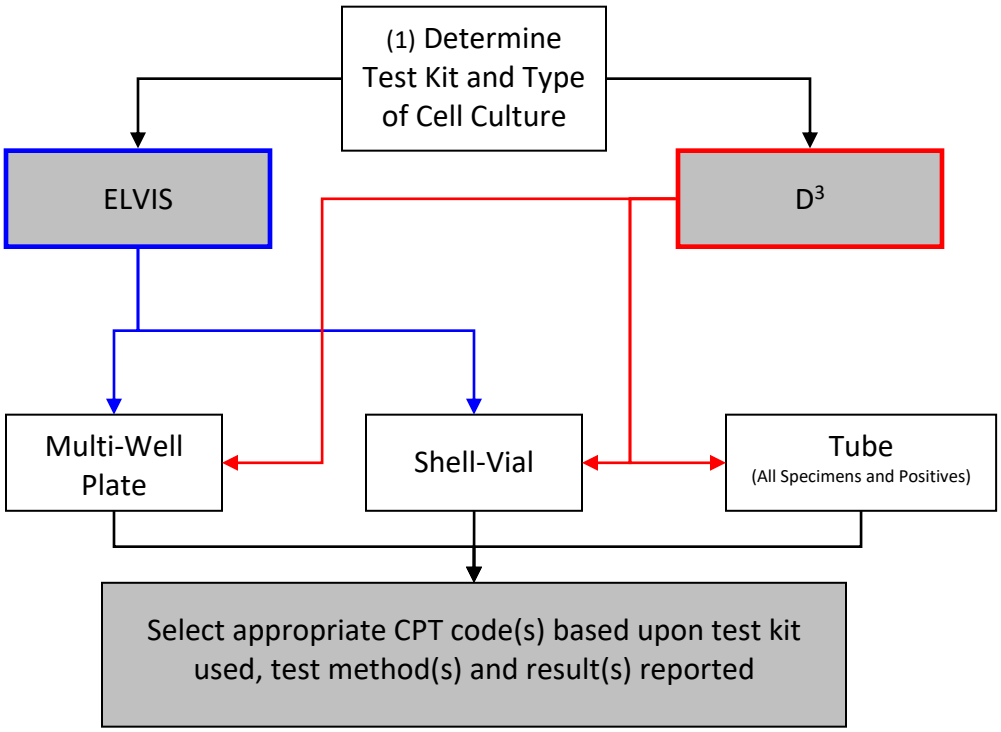
Coding Diagram



[25] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

Herpes Family Testing Solutions

Herpes Family Testing Coding Roadmap



Herpes Family Testing CPT Code Descriptors (Reference)

CPT	Description
87140	Culture, typing; immunofluorescent method, each antiserum
87252	Virus isolation; tissue culture inoculation, observation, and presumptive identification by cytopathic effect
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus
87255	Virus isolation; including identification by non-immunologic method, other than by cytopathic effect (eg, virus specific enzymatic activity)

ELVIS® HSV ID Test System and
ELVIS HSV ID and D³ Typing Test System

Coding for Herpes Simplex Virus Identification (ELVIS)[26]

Cell Culture Method	CPT
Tube	Not Applicable
Multi-Well Plate	87255
Shell-Vial	87255

Coding for Herpes Simplex Virus Typing (ELVIS)[26]

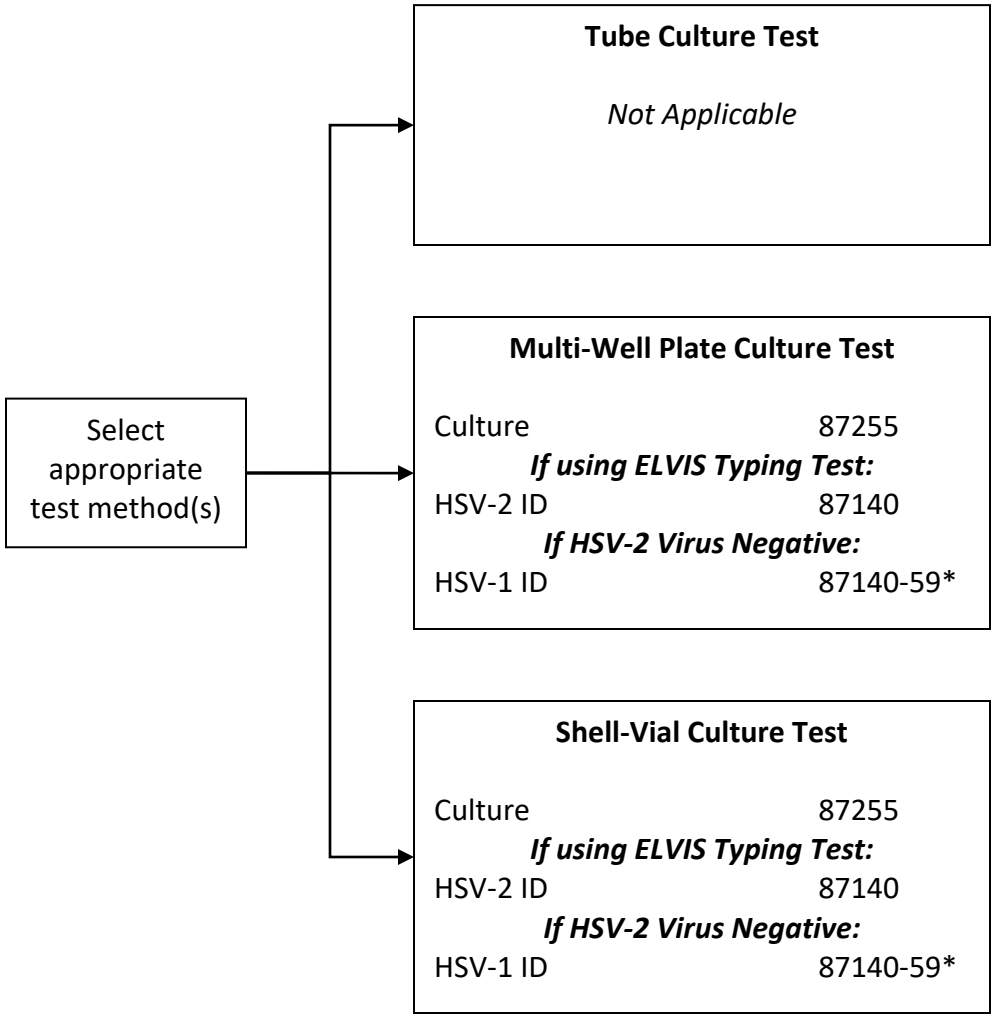
Description	CPT	Modifier (if necessary)[27]
HSV-2	87140	Not Applicable

Blue-cell-positive monolayers with no HSV-2 fluorescence must be stained with appropriate solution to confirm detection of HSV-1.[28]

Description	CPT	Modifier (if necessary)[56]
HSV-1	87140	59

[26] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).
[27] For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.
[28] See product insert.

Coding Diagram



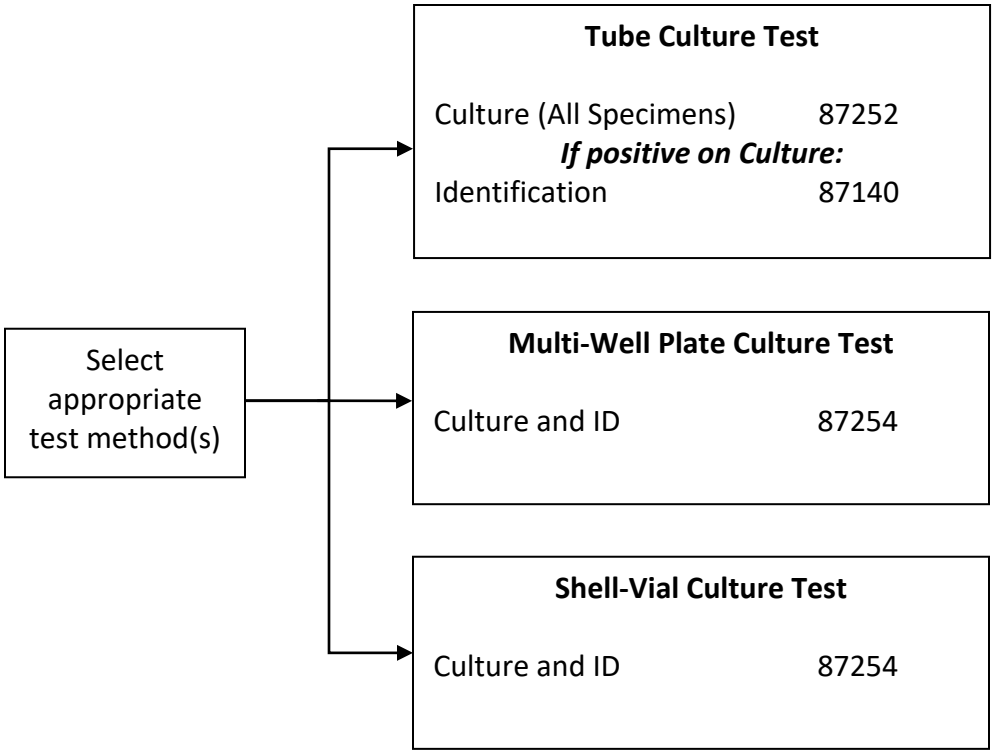
* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

D[3] DFA Herpes Simplex Virus Identification Kit

Coding for Herpes Simplex Virus Identification (D[3])[29]

Cell Culture Method	CPT
Tube: All Specimens	87252
Tube: Positives	87140
Multi-Well Plate	87254
Shell-Vial	87254

Coding Diagram



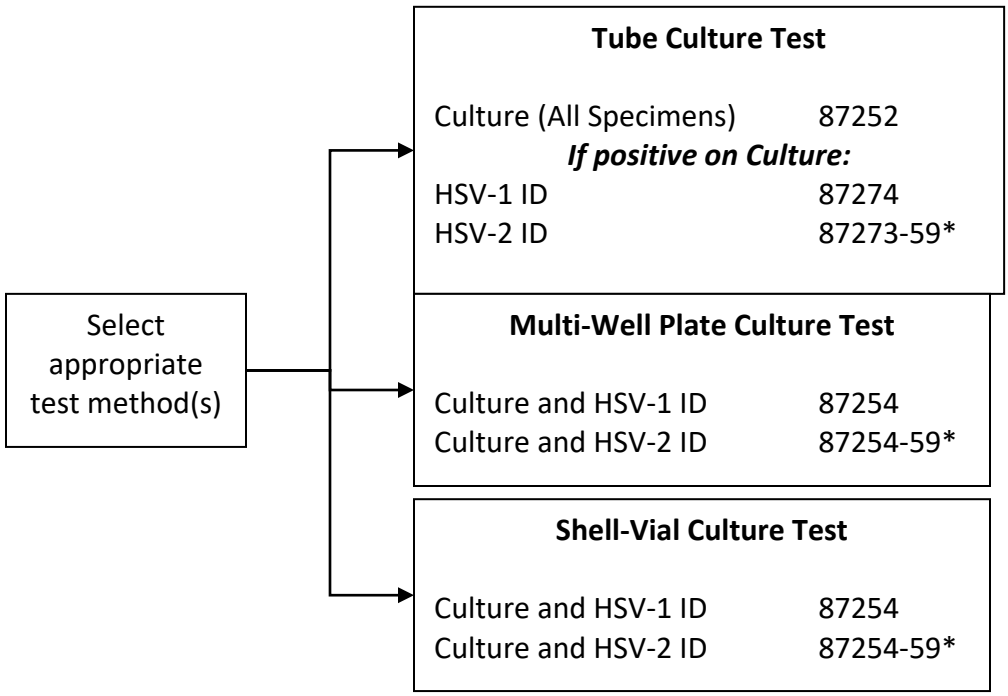
[29] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

D^3 DFA Herpes Simplex Virus Identification and Typing Kit

Coding for Herpes Simplex Virus Identification and Typing (D^3)[30]

Cell Culture Method	Description	CPT
Tube: All Specimens	Culture	87252
Tube: Positives	HSV-1	87274
Tube: Positives	HSV-2	87273-59*
Multi-Well Plate	HSV-1	87254
	HSV-2	87254-59*
Shell-Vial	HSV-1	87254
	HSV-2	87254-59*

Coding Diagram



* For laboratory reporting purposes, modifier 59 is used to report procedures that are distinct or independent, such as performing the same procedure (that uses the same procedure code) for testing of a different specimen or different strain. Use modifier 59 when separate results are reported for different species or strains described by the same CPT Code (AMA CPT Assistant, May 2009 Vol 19 Issue 5). Alternatively, it is possible that when reporting multiple results using the same CPT code, some payers may not require use of a modifier and/or may require use of the units of service box on the claim form.

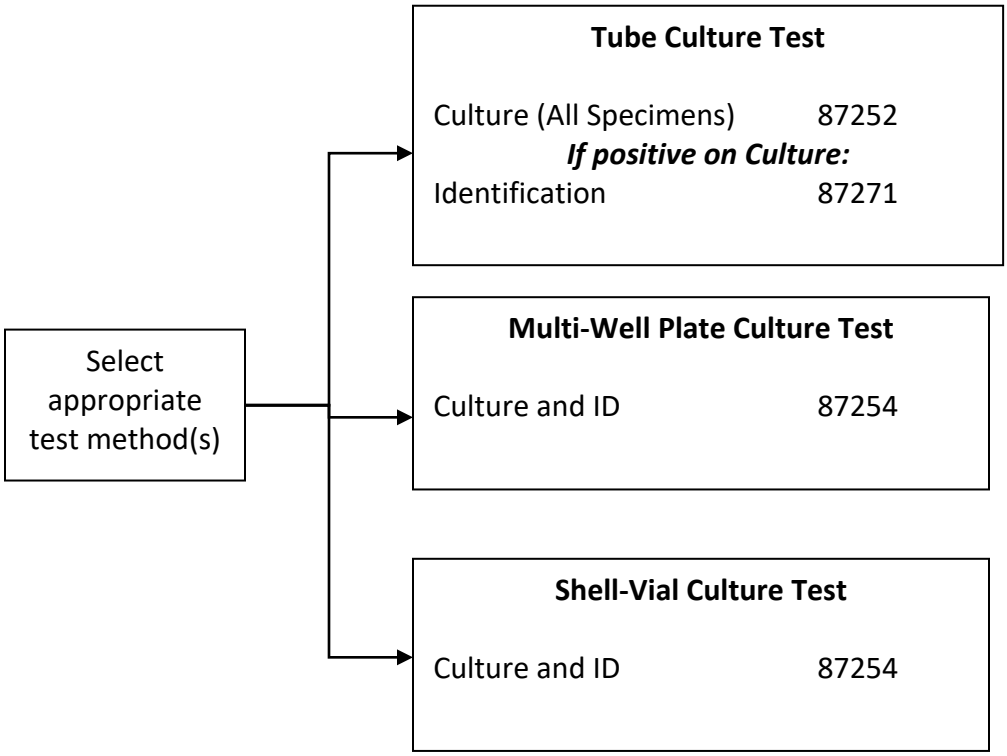
[30] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

D[3] DFA Cytomegalovirus Immediate Early Antigen Identification Kit

Coding[31]

Cell Culture Method	CPT
Tube: All Specimens	87252
Tube: Positives	87271
Multi-Well Plate	87254
Shell-Vial	87254

Coding Diagram



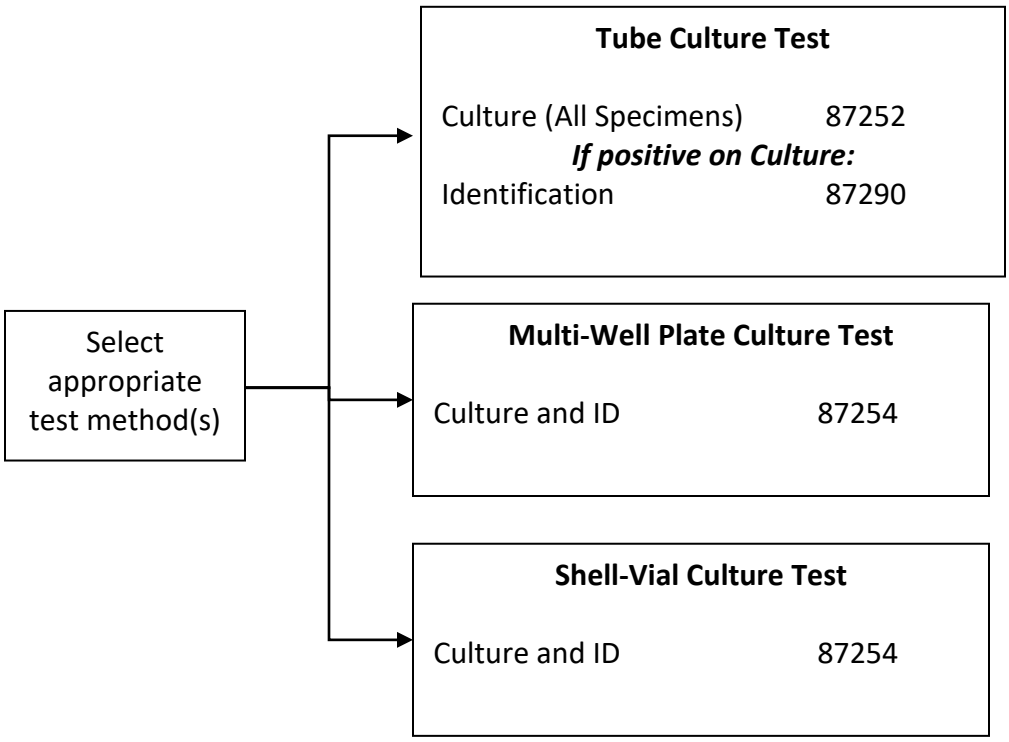
[31] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

D[3] DFA Varicella-zoster Virus Identification Kit

Coding[32]

Cell Culture Method	CPT
Tube: All Specimens	87252
Tube: Positives	87290
Multi-Well Plate	87254
Shell-Vial	87254

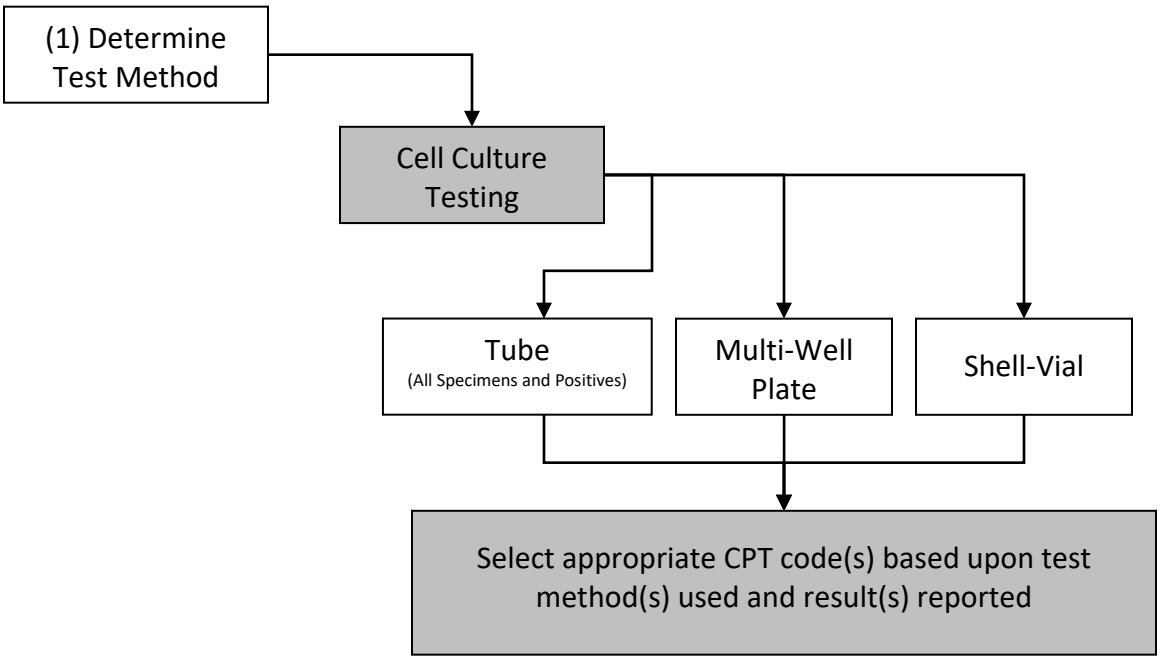
Coding Diagram



[32] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

Enterovirus Testing Solutions

Enterovirus Testing Coding Roadmap



Enterovirus Testing CPT Code Descriptors (Reference)

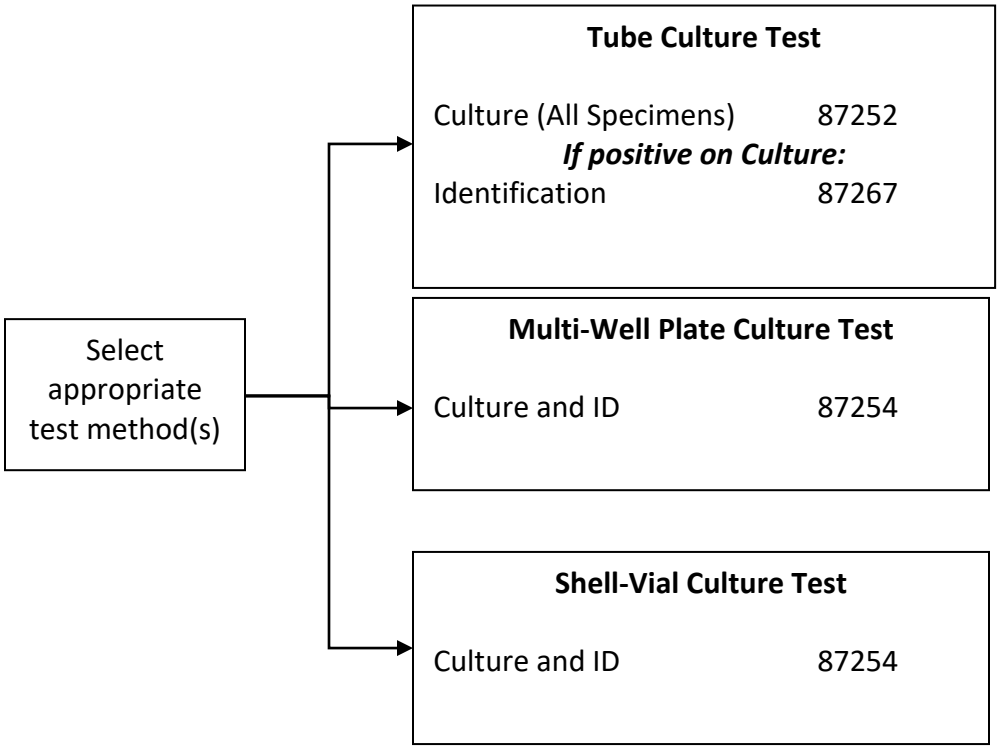
CPT	Description
87140	Culture, typing; immunofluorescent method, each antiserum
87252	Virus isolation; tissue culture inoculation, observation, and presumptive identification by cytopathic effect
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus

D³ IFA Enterovirus Identification Kit

Coding[33]

Cell Culture Method	CPT
Tube: All Specimens	87252
Tube: Positives	87267
Multi-Well Plate	87254
Shell-Vial	87254

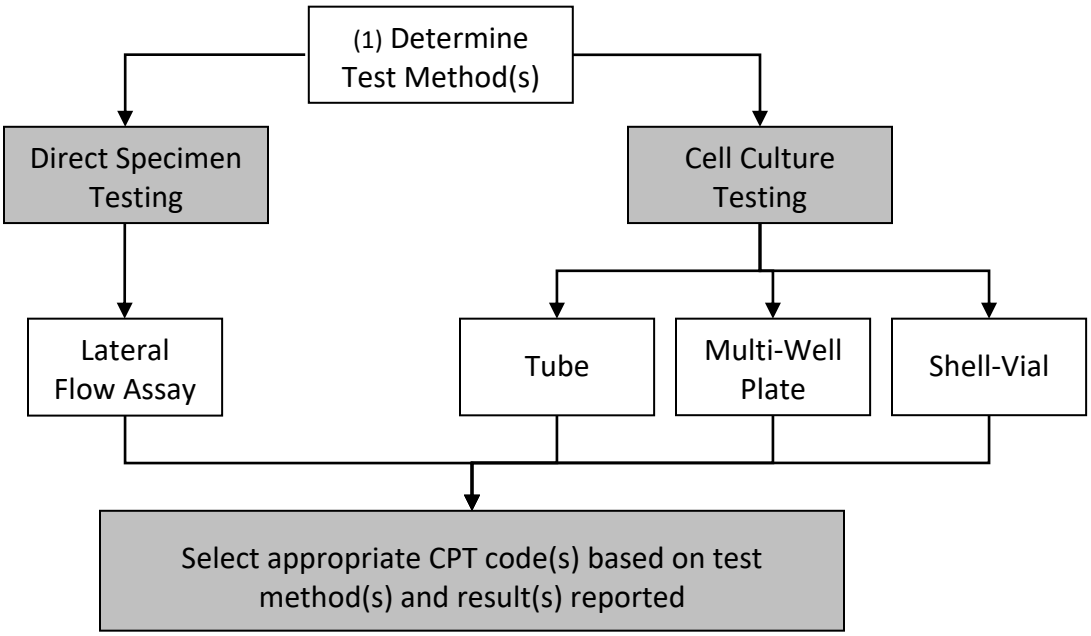
Coding Diagram



[33] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).

Chlamydia Testing Solutions

Chlamydia Testing Coding Roadmap



Chlamydia Testing CPT Code Descriptors (Reference)

CPT	Description
87110	Culture, chlamydia, any source
87140	Culture, typing; immunofluorescent method, each antiserum
87810	Infectious agent antigen detection by immunoassay with direct optical observation; Chlamydia trachomatis

D[3] DFA Chlamydiae Culture Confirmation Kit

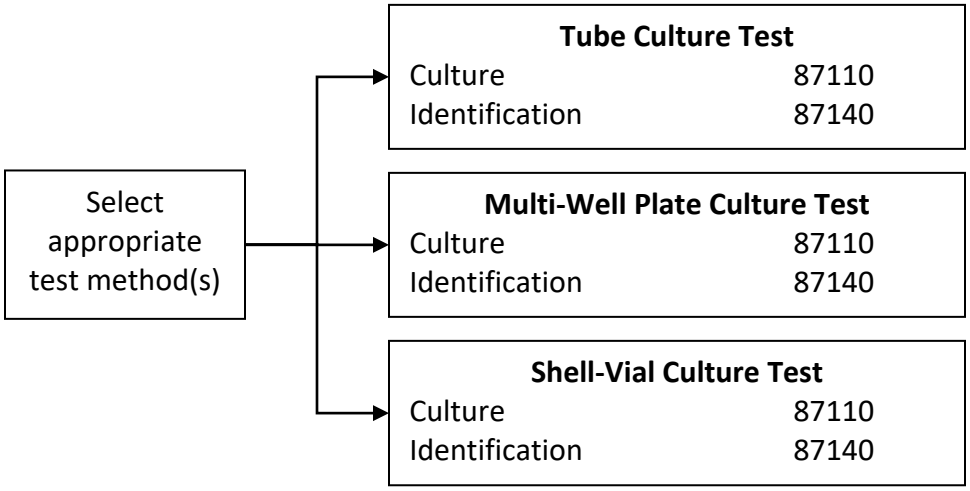
Coding for Cell Culture Testing[34]

Cell Culture Method	CPT
Tube	87110
Multi-Well Plate	87110
Shell-Vial	87110

Coding for Cell Culture Identification[34]

Cell Culture Method	CPT
Tube	87140
Multi-Well Plate	87140
Shell-Vial	87140

Coding Diagram



IN1019000EN00 (09/21)

[34] It is the sole responsibility of the health care provider of service to verify reimbursement policies and select the appropriate CPT and ICD-9-CM codes to accurately reflect patient condition(s) and testing procedure(s).