Centers for Medicare and Medicaid Services Clinical Laboratory Fee Schedule Annual Laboratory Public Meeting July 31, 2017

Anthony Sireci, MD, Msc Association for Molecular Pathology



Outline

- Pharmacogenomics Procedures (81X30-81X36)
- Human Platelet Antigen Procedures (81X15-81X22)
- Heme-related Genetic Analysis Procedures, full sequence, common variants, familial variants and del/dup for F9, G6PD, and hemoglobin alpha and beta (81X25, 81X37-81X40, 81257-81X69, and 813X1-813X4)
- Hereditary Peripheral Neuropathy Genomic Sequencing Procedure (814X5)
- Oncology-related Procedures
 - Common Variants (81X23-24)
 - Targeted Exon or Full Gene Procedures (81X04-05 and 813XX)
- Infectious Disease Procedures (876XX-87X6X and 02X1T)
- Reconsidered Procedures (81327)



Basis for Crosswalk Recommendations

- Analysis of:
 - Analytical methods employed
 - Overall resources utilized
 - Types of genetic variants tested (e.g., SNPs, deletions, etc.,.)
 - Amount of genetic material interrogated



Background: 81X30-36 Pharmacogenomics Codes

New Code	Descriptor
81X30	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)
81X31	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3,*4, *5 *6, *7)
81X32	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)
81X33	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant
81X34	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, $*5$)
81X35	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)
81X36	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)

Test Purpose and Method: 81X30-36 Pharmacogenomics Codes

Purpose: to identify genetic variants in patients which impact drug metabolism and lead to altered dosing of the drug

Methods: PCR amplification followed by a genotyping for single nucleotide germline variants or fragment analysis for repeat expansion variants



Crosswalk Recommendations: 81X30-36 Pharmacogenomics codes

New Code	Gene name	Crosswalk Recommendation	Descriptor	Rationale
81X30	CYP3A4	81374 X 2	HLA Class I typing, one antigen equivalent (eg, B*27), each	The test methods and materials used to query 2 SNPs are comparable to twice those required for one SNP.
81X31	CYP3A5	81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)	The test methods and materials used to test 6 SNPS in CYP3A5 are comparable to those used to query 5 SNPS in CYP2C19.
81X32	DPYD	81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9)(eg, drug metabolism), gene analysis, common variants (eg. *2, *3, *5, *6)	The test methods and materials used to query 4 SNPs are comparable across both assays.
81X33	INFL3	81241	F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis; Leiden variant	The test methods and materials used to detect the type of point mutation tested for in the IFNL3 gene are comparable to that for F5.
81X34	SLCO1B1	81376	HLA Class II typing, low resolution, one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or DPA1), each	The test methods and materials used to detect one SNP in the SLCO1B1 gene are comparable to that for HLA class II typing.
81X35	TPMT	81374 X 2	HLA Class I typing, one antigen equivalent (eg, B*27), each	The test methods and materials used to query 2 SNPs are comparable to twice those required for one SNP.
81X36	TYMS	81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (ie, exons 14, 15)	The test methods (eg, PCR followed by CE analysis) and materials used are comparable for the detection of each of these tandem repeat variants.

Background: 81X15-81X22 Human Platelet Antigen Codes

N - C	
New Code	Descriptor
81X15	Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-1a/b (L33P)
81X16	Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-2a/b (T145M)
81X17	Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-3a/b (I843S)
81X18	Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-4a/b (R143Q)
81X19	Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), common variant (eg, HPA-5a/b (K505E))
81X20	Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-6a/b (R489Q)
81X21	Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-9a/b (V837M)
81X22	Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura) gene analysis, common variant, HPA-15a/b (S682Y)

Test Purpose and Method: 81X15-81X22 Human Platelet Antigen

Purpose: To identify women at risk for neonatal alloimmune thrombocytopenia (NAIT) or platelet recipients at risk for alloimmune thrombocytopenia.

Methods: PCR amplification followed by a genotyping for the specific single nucleotide variants (e.g., Sanger sequencing, RFLP)



Crosswalk Recommendations: 81X15-81X22 Human Platelet Antigen

Crosswalk recommendation for all 81X15-81X22	Descriptor	Rationale
81376	HLA Class II typing, low resolution, one locus (eg, HLA-DRB1, - DRB3/4/5, -DQB1, -DQA1, -DPB1, or DPA1), each	The test methods used, the resources required and the variant types tested for (ie, single nucleotide variants) in all new HPA genes are comparable to that for HLA Class II typing at one locus.

Background: 81X25, 81X37-81X40, 81257-81X69, and 813X1-813X4 Heme-related Genetic Analysis Codes

Constant Spring)

81X69

813X1

813X4

New Code	Descriptor
81X25	F9 (coagulation factor IX) (eg, hemophilia B) full gene analysis
81X37	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; common variant(s) (eg, A, A-)
81X38	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; known familial variant(s)
81X40	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; full gene sequence (13 exons)
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease) gene analysis; for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and

81X58 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant 81X59 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene

analysis; full gene sequence HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene

analysis; duplication/deletion variants HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)

813X2 HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s) 813X3

HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s) HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence

Test Purpose and Method: 81X25, 81X37-81X40, 81257-81X69, and 813X1-813X4 Heme-related Genetic Analysis Codes

Purpose:

- **F9:** to detect genetic variants in patients with factor IX deficiency (hemophilia B) (autosomal recessive)
- **G6PD family of codes:** to detect genetic variants causative of G6PD deficiency (X-linked)
- HBA family of codes: to detect genetic variants causative of alpha thalassemia (autosomal recessive)
- **HBB family of codes:** to detect genetic variants causative of beta thalassemia and other beta hemoglobinopathies (autosomal recessive)

Methods:

- **Full gene sequencing:** bi-directional sequencing of coding regions as well as exon-intron junctions by Sanger sequencing or next generation sequencing.
- **Common variant analysis:** PCR amplification followed by genotyping for single nucleotide variant (SNV); MLPA for del/dup variants
- Familial variant analysis: PCR amplification followed by genotyping for SNV; MLPA for del/dup variants (two variants tested in autosomal recessive conditions)
- **Del/Dup analysis:** generally Multiplexed Ligation-dependent Probe Amplification (MLPA)

Expertise that advances patient care through education, innovation, and advocacy.

www.amp.org



Crosswalk Recommendations: Full Gene Sequencing

New Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X25	F9 (coagulation factor IX) (eg, hemophilia B) full gene analysis	81321	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full gene analysis.	The test methods used for sequencing and the amount of DNA sequenced for F9 are comparable to that for PTEN (priced by gapfill).
81X40	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; full gene sequence (13 exons)	81321	PTEN (phosphatase and tensin homolog) (eg, cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full gene analysis.	The test methods used for sequencing and the amount of DNA sequenced for G6PD both comparable to that for PTEN (priced by gapfill).
81X59	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence	81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	The test methods used for sequencing and the amount of DNA sequenced for HBA1 and HBA2 are both comparable to that for EGFR.
813X4	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence	81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	The test methods used for sequencing and the amount of DNA sequenced for HBB are comparable to that for EGFR.

Crosswalk Recommendations: Known Familial Variant

New Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X38	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; known familial variant(s)	81215	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant	The test methods used and the deletion and substitution types of variants tested for are both comparable to that for BRCA1 known familial variant.
81X58	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant	81215 X 2	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant	The test methods used and the deletion and substitution types of variants tested for are both comparable to that for BRCA1 known familial variant. Since alpha thalassemia is an autosomal recessive condition two variants are generally tested, thus the multiplier of times two.
813X2	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)	81215 X 2	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant	The test methods used and the deletion and substitution types of variants tested for are both comparable to that for BRCA1 known familial variant. Since beta thalassemia is an autosomal recessive condition two variants are generally tested, thus the multiplier of times two.

Crosswalk Recommendations: Common Variants

New Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X37	G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice) gene analysis; common variant(s) (eg, A, A-)	81374 X 2	HLA Class I typing, one antigen equivalent (eg, B*27)	The test methods and materials employed to query 2 SNPs are comparable to twice those required for one SNP.
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease) gene analysis;, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)	81161	DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	The testing methods used and the deletion type of variants tested for are both comparable to that for DMD.
813X1	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HbS, HbC, HbE)	81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)	The materials and methods used for detecting 3 common genotypes in HBB are comparable to those used to detect the 4 common genotypes in CYP2C9.

Crosswalk Recommendations: Duplications/Deletion Variants

New Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X69	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants	81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	The test methods and materials used for detection of del/dups (i.e., MLPA) are comparable across these two procedures.
813X3	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)	81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	The test methods used and materials employed for detection of del/dups (i.e., MLPA) are comparable across these two procedures.

Expertise that advances patient care through education, innovation, and advocacy.

www.amp.org



Background: 814X5 Hereditary Peripheral Neuropathy Genomic Sequencing Procedures

New Code	Descriptor
814X5	Hereditary peripheral neuropathies panel (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, and SPTLC1)



Test Purpose and Method: 814X5 Hereditary Peripheral Neuropathy

Purpose: To detect pathogenic or likely pathogenic sequence variants and small insertion or deletions (indels) in relevant genes from patients with peripheral neuropathy phenotype.

Methods: Bi-directional sequencing (e.g., sanger sequencing, next generation sequencing) of coding regions of >5 genes to detect single nucleotide variants and small indels.



Crosswalk Recommendation: 814X5 Hereditary Peripheral Neuropathy

New code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
814X5	Hereditary peripheral neuropathies panel (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, and SPTLC1)	81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN	The amount of DNA sequenced and the methods employed (eg., NGS) are comparable between these two assays.

Expertise that advances patient care through education, innovation, and advocacy.

www.amp.org



Background: 81X23-24 Oncology Common Variants Codes

New Code	Descriptor
81X23	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)
81X24	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)



Test Purpose and Method: 81X23-24 Oncology Common Variants

Purpose: To detect a small set of known oncogenic mutations which are helpful in the diagnosis of certain cancers and have prognostic significance.

Methods: PCR amplification followed by a genotyping method (i.e., sanger sequencing)



Crosswalk Recommendations: 81X23-24, Oncology Common Variants

New Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X23	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)	81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variant in exon 2 (eg, codons 12 and 13).	The test method and materials used to assay two variants at the same or contiguous codons is comparable across the two assays.
81X24	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)	81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)	The test method and materials used to assay two variants in distant codons is comparable across the two assays.

Background: 81X04-05 and 813XX, Oncology Targeted Exon or Full Gene Procedures

New Code	Descriptor
81X04	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndromes, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; full gene sequence
81X05	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndromes, myeloproliferative neoplasms, chronic myelomonocytic leukemia) gene analysis; targeted sequence analysis (eg, exon 12)
813XX	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) gene analysis, targeted sequence analysis (eg, exons $3-8$)



Test Purpose and Method: 81X04-05 and 813XX, Oncology Targeted Exon or Full Gene Procedures

- Purpose: To detect somatic mutations in genes associated with the diagnosis or prognosis of certain cancer types.
- Methods: PCR amplification followed by a genotyping method (i.e., sanger sequencing)



Crosswalk Recommendations: 81X04-05 and 813XX Oncology Targeted Exon or Full Gene Procedures

New Code	Short Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81X04	ASXL1 (additional sex combs like 1, transcriptional regulator) gene analysis; full gene sequence	81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis.	The test methods used for sequencing analysis and the amount of DNA sequenced are comparable to that for PMS2 (priced by gapfill).
81X05	ASXL1 (additional sex combs like 1, transcriptional regulator) gene analysis; targeted sequence analysis (eg, exon 12)	81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence	The test methods used for sequencing analysis and the amount of DNA sequenced of 1 large exon are comparable to sequencing the CEBPA large exon (priced by gapfill).
813XX	RUNX1 (runt related transcription factor 1) gene analysis, targeted sequence analysis (eg, exons 3 – 8)	81235 X 2	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	The testing methods used for sequencing and the amount of DNA sequenced are comparable to twice that used to analyze EGFR.

Background: 876XX-87X6X and 02X1T Infectious Disease Codes

New Code	Descriptor
876XX	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
87X6X	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique

Other Code	Descriptor
02X1T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)(ie, genotyping)

Expertise that advances patient care through education, innovation, and advocacy.





Test Purpose and Method: Infectious Disease

- Purpose: To diagnose infection with viral pathogens; to determine viral genotype
- Methods: amplified probe technique; single or multiplexed



Crosswalk Recommendations: 876XX-87X6X and 02X1T Infectious Disease Codes

Code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
876XX	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique	87801	Infectious agent detection by nucleic acid (DNA or RNA); multiple organisms; amplified probe(s) technique	The test methods, including reverse transcription of single stranded RNA virus, and resources required for RSV testing of multiple strains are comparable to the identification of multiple organisms coded by 87801.
87X6X	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique	87502	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple subtypes, includes reverse transcription, when performed, and multiplexed amplified probe technique, first two types or sub-types	The test methods, including reverse transcription of the single stranded RNA virus, and resources required for Zika NAA testing are comparable to the identification of multiple types of influenza.
02X1T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)	87624	Human Papillomavirus (HPV). High-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)	The test method and materials used are similar to those used in the existing code for HPV high risk screening (ie, amplified probe technique).

Background: 81327 Septin 9

Revised code	Descriptor
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis



Test Purpose and Method: 81327 Septin 9

 Purpose: Analysis for blood-based CRC screening. Real-time PCR-based measurement of methylated SEPT9 DNA. Previously coded in Tier 2 under 81401

Methods: promotor methylation analysis



Crosswalk Recommendation: 81327 Septin 9

Revised code	Descriptor	Crosswalk Recommendation	Descriptor	Rationale
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis		MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non- polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis	SEPT9 descriptor was recently corrected to identify promoter methylation which uses comparable resources and a test method to that of the MLH1 promoter.

Expertise that advances patient care through education, innovation, and advocacy.

