

**Providers' perspective on  
reimbursement of genetic technologies  
and services:  
A laboratorian's perspective**

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# Coding, billing and reimbursement for laboratory testing and services

- Codes are the language of reimbursement
- Procedure coding
  - Level I: Current Procedural Terminology (CPT) code (AMA)
    - Five digit numbers
    - Identify specific analytes, methodologies, assays, stains, consultations, interpretations, etc.
    - Code modifiers
      - Two digit code added to a five digit procedure code
  - Level II: HCPCS codes (CMS)
    - Begin with a letter (A-V) followed by four numbers
    - For procedures not identify in CPT codes

# Coding, billing and reimbursement for laboratory testing and services

- CPT codes are the means by which payers match up a service on a claim form to the payment rate
- All Medicare, state Medicaid and many private or commercial insurance payers require the use of CPT codes to identify the services
- International classification of disease-9 codes
  - Identify diagnoses

# Molecular Diagnostics CPT codes use for genetic testing

- 83890 molecular isolation or extraction
- 83891 isolation or extraction of highly purified nucleic acid
- 83892 enzymatic digestion
- 83893 dot/slot blot production
- 83894 separation by gel electrophoresis (e.g.. agarose, polyacrilamide)
- 83896 nucleic acid probe, each
- 83897 nucleic acid transfer (eg. Southern, Northern)
- 83898 amplification of patient nucleic acid (e.g.. PCR, LCR) single primer pair, each primer pair)
- 83901 amplification of patient nucleic acid, multiplex, each reaction
- 83902 reverse transcription
- 83903 mutation scanning, by physical properties (e.g.. Single stranded conformation polymorphisms(SSCP), heteroduplex, denaturing gradient gel electrophoresis (DGGE), RNA'ase A), single segment, each
- 83904 mutation identification by sequencing, single segment, each segment
- 83905 mutation identification by allele specific transcription., single segment, each segment
- 83912 interpretation and report

## Medicare Laboratory Fee Schedule for 2004

	Short description	National	00511	00904	00910	05535	31140
HCPC		Limit	Loc 00	Loc 00	Loc 00	Loc 00	Loc 00
83890	Nucleic acid isolation	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83891	Isolation highly purified	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83892	Restriction enzyme each	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83893	Dot/slot/blot	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83894	Gel electrophor	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83896	Nucleic acid probe, each	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83897	Nucleic transfer	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60
83898	Nucleic ampli	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83901	Nucleic ampli/multiplex	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83902	Reverse transcription	\$19.83	\$17.69	\$5.47	\$19.83	\$5.75	\$19.83
83903	Mutation scan	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83904	Mut seq	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83905	Mut allele transcription	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83906	Mut allele translation	\$23.42	\$5.37	\$23.42	\$20.79	\$5.75	\$23.42
83912	Genetic interpretation	\$5.60	\$5.51	\$5.47	\$4.45	\$5.60	\$5.60

# Financial Analysis

- **VCU Medical Center**
  - Medical College of Virginia Hospitals (MCVH), MCV Associated Physicians and VCU Medical School
- **MCVH**
  - 650 bed hospital
  - Tertiary center
  - Inner city
- **Molecular Diagnostics Laboratory**
  - Infectious Disease
  - Oncology
  - Hematology
  - Inherited Disorders
  - CY '03 performed 13,209 tests

# Fragile X Syndrome

- **Most common cause of inherited mental retardation (1/1,200 males and 1/2,500 females)**
- **The fragile X gene (FMR1) contains a tandemly repeated trinucleotide sequence (CGG) near its 5' end.**
- **The number of CGG repeats**
  - normal population varies from 6 to approximately 50.
  - premutations of approximately 50 to 200 repeats (45-55 copies in the "grey zone")
  - full mutations of more than approximately 200 repeats.
- **DNA studies:**
  - **Polymerase chain reaction (PCR) allows sizing of the PCR products. PCR permits accurate sizing of alleles in the normal, the premutation, or the "grey zone" size ranges.**
  - **Southern blotting allows both size of the repeat segment and methylation status. Accurately detects alleles in all size ranges, but precise sizing is not possible.**
  - **Many labs have both methods available**

# Fragile X Syndrome

## Southern Hybridization Analysis

Description	CPT code	VCUMC Cost	VA Medicare expect
Nucleic acid isolation highly purified	83891	15.6	5.47
Enzyme digestion	83892x2	35.7	10.94
Gel electrophoresis	83894x2	38.5	10.94
Southern blot	83897x2	59.7	10.94
Nucleic acid probe	83896	76.84	5.47
Interpretation and report	83912-26	40	18.54
<b>Total</b>		<b>266.34</b>	<b>62.30</b>

## PCR

Description	CPT code	VCUMC Cost	VA Medicare expect
Amplification	83898	34.0	23.42
Nucleic acid isolation	83890	15.6	5.47
Separation	83903	32.0	23.42
Interpretation and report	83912-26	35.0	18.54
<b>Total</b>		<b>116.6</b>	<b>70.85</b>



# Immunoglobulin Gene Rearrangement by PCR

- Extremely important in the diagnosis of lymphoma and leukemia
- Structural analysis of the B lymphocyte antigen receptor genes , when properly interpreted, can detect monoclonal proliferation of lymphocytes
- Identification of a clonal proliferation of lymphoid cells is central to the diagnosis of lymphoma and lymphocytic leukemia (differential diagnosis of reactive lymphadenopathy versus lymphoma or a nonlymphoid malignancy)

# Immunoglobulin Gene Rearrangement by PCR

Description	CPT code	VCU Cost	VA Medicare expect
Nucleic acid extraction	83891	24.75	5.47
Amplification	83898 x 3	118.62	70.24
Separation	83903 x 3	93	70.24
Interpretation and report	83912-26	40	18.54
<b>Total</b>		<b>276.36</b>	<b>164.53</b>

# Factor V Leiden

- Factor V Leiden is the most common hereditary blood coagulation disorder in the United States.
  - **5% of the Caucasian**
  - **1.2% of the Afro-American population.**
- Factor V Leiden increases the risk of venous thrombosis
  - **3-8 fold for heterozygous**
  - **30-140 fold, for homozygous individuals**
- Venous thrombosis and Pulmonary embolism (PE)
  - Sinus vein thrombosis
  - Mesenteric vein thrombosis
  - Budd-Chiari syndrome, Arterial clots in selected patients (some smokers)
- Possibly with stillbirth or recurrent unexplained miscarriage  
Preeclampsia and/or eclampsia (toxemia while pregnant)

# Factor V Leiden

<b>Description</b>	<b>CPT code</b>	<b>VCUMC Cost</b>	<b>VA Medicare expect</b>
Nucleic acid isolation	83890	9.69	5.47
Nucleic acid probe, each	83896 x 4	21.8	21.88
Enzymatic digestion	83893 x 4	22.5	21.88
Interpretation and report	83912-26	18	18.54
<b>Total</b>		<b>71.99</b>	<b>67.77</b>

# VCUMC Reimbursement for technical CPT Codes

Payer	% Claims paid	Reimbursement
Medicare	89	NLA
Medicaid	72	NLA
BC/BS PPO	80	~ NLA
BC/BS HMO	75	~ NLA
Aetna	78	~ NLA
Cigna PPO	61	~ NLA
Alliance PPO	85	~ NLA

# Reimbursement Interpretation and Report (83912-26)

- Interpretation of genetic tests is
  - extremely complex
  - challenging
  - genotype-phenotype correlations
  - clinico-pathological correlation
  - genetic counseling implications

# VCUMC Reimbursement for CPT Code 83912-26

Payer	% Claims paid	Reimbursement
Medicare	93	\$18.57
Medicaid	93	\$18.57
BC/BS PPO	84	\$5.47
BC/BS HMO	81	\$5.47
Aetna	86	\$5.47
Cigna PPO	78	\$5.47
Alliance PPO	61	\$5.47

# Factors affecting access to genetic testing

- Genetic testing utilization is increasing
- Laboratory fee schedule was "frozen" for five years - from 1998 through 2002 - then got a 1.1% increase and it was frozen again from 2004 through 2008.
- Costs still continue to increase significantly for laboratories - e.g. cost of labor, cost of technology, inadequate reimbursement for inpatient testing with prospective payment systems, managed care etc.
- Ability to cost shift is extremely limited





# Reimbursement for Molecular CPT Codes

	Cost	Medicare Reimbursement
Quant t(9;22)	138.5	51.65
HIV viral load	99.18	114.36
HCV Viral load	99.18	58.65

# Impact of patents on access to genetic testing

- Increase cost of testing
  - Royalty payment for patented procedures
    - 9-15% receipts
  - Royalty payment for patented gene/sequences
    - Up-front + Flat fee/test
      - BioRad Laboratories acquired patents for HFE and developed commercial kits. License to laboratories w/up-front fee plus \$20/test\*
    - One time payment + % of charges

\* Merz et al Nature 2002, 415: 577-579

# Effects of patents and licenses on provision of clinical genetic testing services

Survey of 122 Laboratory directors

Institutional affiliation	<i>n</i> (%)
Company	19 (16)
University	73 (60)
Federal	16 (13)
Nonprofit	80 (66)
Private hospital	64 (52)
Other	10 (8.2)

Totals do not add up to 100% because response options were not mutually exclusive.

# Effects of patents and licenses on provision of clinical genetic testing services

Genetic test	# Labs stopped performing this test
Apolipoprotein E (ApoE)	9
Hereditary Breast/Ovarian Cancer (BRCA1/BRCA2)	9
Duchene/Becker muscular dystrophy	5
Hereditary Hemochromatosis (HFE)	5
Myotonic dystrophy	4
Canavan Disease	4
Spinocerebellar ataxia (SCA1, SCA2, SCA3, SCA6)	4
Adenomatous polyposis of the colon	2
Fragile X syndrome	1
Factor V Leiden	1

# Conclusions

- Genetic tests are being reimbursed by Medicare, Medicaid and Third Party Payers
- Level of reimbursement does not cover test costs
- Impact of patents on genetic test access needs to be further explored