Recent Updates and Current Trends in CPT Coding for Laboratory and Pathology Services

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SPEAKER DISCLOSURE

• I have no disclosable conflicts of interest related to the subject matter presented in this presentation.
Presentation Goals

- Discuss updates to CPT 2016 as they pertain to the Pathology & Laboratory sections of CPT and,
- Discuss trends for pathology and laboratory coding in CPT related to CMS directives

Changes for CPT 2016

- Immunofluorescent/Immunohistochemistry Studies
- Obstetric Panel
- Chemistry
  - Chromatography and Mass Spectrometry
- Serology
- Microbiology
- Molecular Pathology
  - Tier 1/Tier 2
  - Genomic Sequencing
  - MAAA
Immunofluorescent Studies

Image Courtesy of
www.nature.com/nrneph/journal/v3/n5/fig_tab/ncpneph0476_F3.html

Image Courtesy of www.en.wikipedia.org/wiki/Immunofluorescence
Immunofluorescent Microscope

Image Courtesy of www.microscopyu.com/articles/fluorescence/fluorescenceintro.html

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Immunofluorescent Technique

Image Courtesy of www.nature.com/jid/journal/v133/n1/fig_tab/jid2012455f1.html#figure-title

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Immunofluorescent Studies

Revised code **88346**
- Immunofluorescence reported *per specimen* as an initial single antibody stain procedure (& removed “direct method”)

Deleted code **88347**
- See 88346, 88350

New code **88350**
- Add-on code to 88346
- Reported per additional single antibody stain procedure

Added exclusionary parenthetical
- Do not report 88346, 88350 with fluorescent in situ hybridization codes (88364-88369, 88373, 88374, 88377)

Immunofluorescent Studies

Revised cross-references following codes 86255 and 86256, direct user to indirect fluorescence staining and evaluation 88346, 88350.

To prevent misuse, exclusionary parenthetical note was added following 88350 to restrict reporting codes 88346 and 88350 with codes in situ hybridization studies 88364-88369, 88373, 88374, and 88377.
Immunofluorescent Studies Physician Payment

-  88346: Brought to CPT for clarification due to identification in the RUC CMS/Other source screen for codes with Medicare utilization over 250,000.
- New coding structure resulted in a lower RVU for 88346, which is now the initial single antibody stain procedure and is not based on direct vs indirect method.
- 88350 is the same as the base code, 88346, except the physician is evaluating an additional immunofluorescence stain on the same specimen using a different primary antibody.

Immunohistochemistry

Image Courtesy of Hoffman, G. Seeing Is Believing: Use of Antibodies in Immunocytochemistry and In situ Hybridization. (Baltimore, Maryland: Morgan State University), fig 4, @ 2008 by Hoffman.
**Immunohistochemistry**

**Category I**
**Pathology and Laboratory: Surgical Pathology**

88342  Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure

#188341  each additional single antibody stain procedure (List separately in addition to code for primary procedure)

88344  each multiplex antibody stain procedure

*(Do not use more than one unit of 88341, 88342, or 88344 for the same each separately identifiable antibody per specimen)*

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**Obstetric Panel**

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80081 Obstetric Panel (includes HIV testing)

This panel must include the following:
- Blood count, complete (CBC), and automated differential WBC count (85025 or 85027 and 85004)
- OR
- Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009)
- Hepatitis B surface antigen (HBsAg) (87340)

HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result (87389)
- Antibody, rubella (86762)
- Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART) (86592)
- Antibody screen, RBC, each serum technique (86850)
- Blood typing, ABO (86900) AND
- Blood typing, Rh (D) (86901)

Establish new HIV obstetric panel code (80081)

Obstetric Panel

The HIV obstetric panel code 80081 differs from the existing obstetric panel code 80055 in that it includes HIV testing. The test for HIV-1 antigens(s), with HIV-1 and HIV-2 antibodies (87389) has been listed as a component of the HIV obstetric panel.
Evaluation of Four Qualitative Third-Generation HIV Antibody Assays and the Fourth-Generation Abbott HIV Ag/Ab Combo Test


Obstetric Panel

Instruction was added to direct the user not to report code 80081 when syphilis screening is performed using a treponemal antibody approach (86780).

Instead, the individual codes should be used for the tests performed in the obstetric panel.
Obstetric Panel

The HIV obstetric panel (80081) includes a defined list of tests.

To report code 80081, all of the tests listed in the panel definition must be performed, with no substitutions.

If fewer tests are performed than listed in the panel code, the individual code numbers for each test should be listed rather than the panel code.

Obstetric Panel

The panel components are not intended to limit performance of other tests.

If tests are performed in addition to the tests listed for a panel, the additional tests would be reported separately in addition to the panel code.
Organ or Disease-Oriented Panels

Two or more panel codes that include any of the same constituent tests performed from the same patient collection should not be reported.

If a group of tests overlaps 2 or more panels, the panel code that incorporates the greater number of tests to fulfill the code definition is reported and the remaining tests are reported using individual test codes (eg, do not report code 80047[basic panel] in conjunction with code 80053 [comp panel]).

Chemistry Chromatography and Mass Spectrometry
Chromatography and Mass Spectrometry

- Definitive drug testing now includes mass spectrometry (any type, single or tandem) and liquid chromatography mass spectrometry (any type, single or tandem)
- Presumptive testing includes chromatography without mass spectrometry or mass spectrometry without adequate drug resolution by chromatography (MS-TOF, DART, DESI, LDTD, MALDI). LC-MS, LCMS/MS, spectrometry (TLC, HPLC, GC, etc)

Codes 82542 and 83789 have been revised to simplify reporting for chromatography and mass spectrometry testing.

To reflect 2015 code set revisions, codes 82486-82489, 82491, 82492, 82541, 82543, 82544, and 83788 and part of the guidelines associated with chromatography reporting have been deleted.
Chromatography and Mass Spectrometry

Codes 82542 and 83789:

Revised to specify all methods included for chromatography and mass spectrometry tests.

Include reporting for time-of-flight (TOF), liquid and gas chromatography procedures (LC, GC), MALDI and other mass spectrometry and chromatography methods.

Chromatography and Mass Spectrometry

Top 25 lab tests based on Medicare Part B payments* in 2014:

1. Blood test, thyroid-stimulating hormone (TSH) (84443)
2. Blood test, comprehensive group of blood chemicals (80053)
3. Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)
...
12. Chemical analysis using chromatography technique (82542)

*HHS OIG Data Brief • September 2015 • OEI-09-15-00210
Hepatitis A Antibody

- **86708** Hepatitis A antibody (HAAb); total
- **86709** Hepatitis A antibody (HAAb), IgM antibody

86708 was specific to the detection of total (IgG and IgM) antibodies to Hepatitis A. Revision of 86708 now allows reporting detection of an IgG antibody to Hepatitis A.
Enzyme Immunoassay Infectious Agent Detection

The revision broadens the intent of these codes to include immunoassays other than enzyme immunoassays.
Enzyme Immunoassay Infectious Agent Detection

87301-87451

Examples of types of immunoassays have been added to the parentheticals in codes 87301 and 87449. These codes now allow reporting of infectious agent antigen detection by any immunoassay technique.

Enzyme Immunoassay Infectious Agent Detection (87301-87451)

87301 Infectious agent antigen detection by immunoassay technique, (eg., enzyme immunoassay technique [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semi quantitative, multiple-step method; adenovirus enteric types 40/41

87449 Infectious agent antigen detection by immunoassay technique, (eg., enzyme immunoassay technique [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; multiple-step method, not otherwise specified, each organism
Tier 1 MoPath Procedure Guidelines: Overview

- Code selection based on specific gene analyzed
- Genes described using Human Genome Organization (HUGO) approved gene names
- Gene is typically represented by:
  - Abbreviated gene name, italicized, listed first
  - Followed by full gene name, italicized, in parentheses
- Examples ("eg") do not represent all conditions in which testing of the gene may be indicated
Molecular Pathology (MoPath) Procedure Code Families

- Tier 1 Molecular Pathology Procedures
- Tier 2 Molecular Pathology Procedures
- Genomic Sequencing Procedures and Other Molecular Multianalyte Assays
- Multianalyte Assays with Algorithmic Analyses (Category I and Administrative Code Set).

Tier 2 MoPath Procedure Codes

Revisions to existing codes include: addition of analytes; revised analyte names; and deleted analytes

- **81401**: Revised 1 analyte; Added 2 analytes
- **81402**: Removed 1 analyte
- **81403**: Removed 3 analytes
- **81404**: Removed 3 analytes
- **81405**: Revised 1 analyte
- **81406**: Revised 1 analyte; Added 1 analyte
2016 GSPs Procedure Codes

New code 81412

- Genomic sequence analysis panel for Ashkenazi Jewish associated disorders
- Must include sequencing of at least 9 genes

81412  Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1

2016 GSPs Procedure Codes

New code 81432

- Genomic sequence analysis panel for hereditary breast cancer-related disorders
- Must include sequencing of at least 14 genes

New code 81433

- Indent under 81432
- Duplication/Deletion analysis panel

81432  Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53

81433  duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
2016 GSPs Procedure Codes

New code 81434

- Genomic sequence analysis panel for hereditary retinal disorders (eg, retinitis)
- Must include sequencing of at least 15 genes

81434 Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy); genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A

2016 GSPs Procedure Codes

New code 81437

- Genomic sequence analysis panel for hereditary neuroendocrine tumor disorders
- Must include sequencing of at least 6 genes

New code 81438

- Indent under 81437
- Duplication/deletion analysis panel

81437 Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL

81438 Duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL

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2016 GSPs Procedure Codes

New code 81442

- Genomic sequence analysis panel for Noonan spectrum disorders
- Must include sequencing of at least 12 genes

81442 Noonan spectrum disorders (e.g., Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1

Multianalyte Algorithmic Assays

New code 81490

- Vectra® DA, Crescendo Bioscience, Inc.
- Multiplex immunoassay for rheumatoid arthritis disease activity
- May be performed in adults with rheumatoid arthritis to quantify disease activity
- Result may help predict risk for subsequent joint damage in patients with rheumatoid arthritis

81490 Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score

(Do not report 81490 in conjunction with 86140)
Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score.

**New code 81493**
- Corus® CAD, CardioDx, Inc.
- Gene expression profiling
- May be performed in patients who present with stable symptoms suggestive of obstructive coronary artery disease
- Result indicates the likelihood a patient has obstructive coronary artery disease

81493 Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score.

Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score.

**New code 81525**
- Oncotype DX® Colon Cancer Assay, Genomic Health
- Gene expression profiling of colon cancer tumors
- May be performed on tumor specimens from patients with stage II and III colon cancer to quantitatively assess recurrence risk
- Result is a recurrence score

81525 Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score.
Multianalyte Algorithmic Assays

New code **81528**
- Cologuard™, Exact Sciences, Inc.
- Multi-target stool DNA-based screening for colorectal cancer
- May be performed in patients who are at average risk for colorectal cancer to identify cancerous and precancerous conditions of the colon and rectum

**81528** Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

(Do not report 81528 in conjunction with 81275, 82274)

Multianalyte Algorithmic Assays

New code **81535** and **81536**
- ChemoFX®, Helomics, Corp.
- Cell culture-based assay
- Measures the sensitivity and resistance of tumor-derived malignant epithelial cells to chemotherapeutic agents in vitro

**81535** Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination

**81536** each additional single drug or drug combination

(List separately in addition to code for primary procedure)
Multianalyte Algorithmic Assays

New code 81538
- VeriStrat, Biodesix, Inc.
- Mass spectrometric test for non-small cell lung cancer
- May be performed in patients with advanced non-small cell lung cancer, who are either epidermal growth factor receptor (EGFR) wild-type or EGFR status unknown
- Tumor samples are categorized as good, poor, or indeterminate

81538 Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival

Multianalyte Algorithmic Assays

New code 81540
- CancerTYPE ID, bioTheranostics, Inc.
- Gene expression profiling in order to classify metastatic tumors
- May be performed on tumor specimens from patients diagnosed with malignant disease
- Result is reported as a probability of the most likely main tumor type and subtype

81540 Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype
## Multianalyte Algorithmic Assays

### New code 81545
- Afirma® Gene Expression Classifier, Veracyte, Inc.
- Gene expression analysis in thyroid nodules to identify a benign or suspicious signature
- May be performed in patients with thyroid tumors of indeterminate cytopathology diagnosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81545</td>
<td>Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)</td>
</tr>
</tbody>
</table>

### New code 81595
- AlloMap®, CareDx, Inc.
- Gene expression profiling in heart-transplant recipients
- May be performed in heart-transplant recipients with stable allograft function to determine the probability of acute cellular rejection

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81595</td>
<td>Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score</td>
</tr>
</tbody>
</table>
Protecting Access to Medicare Act of 2014

- A.K.A.: The "doc fix", sunsets the Sustainable Growth Rate (SGR) calculation for adjustments to the Physician Fee Schedule
- Introduced in the 113th Congress on March 26, 2014
- **Passed the House on** March 27, 2014 by voice vote
- **Passed the Senate on** March 31, 2014
- **Signed into law by the President on** April 1, 2014

Section 216: Improving Medicare Policies for Clinical Laboratory Tests
Protecting Access to Medicare Act (PAMA) §216: Overview

PAMA requires a new coding infrastructure to report clinical diagnostics laboratory tests with requisite specificity

The proposed rule allows the coding solution to be:

- HCPCS Level I
  - CPT
- HCPCS Level II
  - CMS G codes

PAMA §216 Coding Provisions

ADLTs

Single Laboratory AND

MAAA Like Criteria OR

FDA Cleared or Approved Tests OR

Sec'y Discretion

CDLTs

FDA Cleared or Approved

Not limited to Single Laboratory

May be currently reported with a CPT Category I or III code
### Codes

<table>
<thead>
<tr>
<th>Bucket #1</th>
<th>Bucket #2</th>
<th>Bucket #3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Tests</strong>&lt;br&gt;Temporary Code</td>
<td><strong>Existing</strong>&lt;br&gt;Tests Medicare Pays&lt;br&gt;1-1-2016</td>
<td><strong>Requested</strong>&lt;br&gt;Establishment of Unique Identifier for Certain Tests</td>
</tr>
<tr>
<td>Secretary shall adopt temporary HCPCS codes to identify</td>
<td>Not to exceed 2 years or longer by Secretary discretion.</td>
<td>For purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for</td>
</tr>
<tr>
<td>New advanced diagnostic laboratory tests</td>
<td>Existing tests for which payment is made under this part as of the date of enactment of this section, if such test has not already been assigned a unique HCPCS code, the Secretary shall--&lt;br&gt;New laboratory tests that are cleared or approved by the FDA</td>
<td>an advanced diagnostic laboratory test&lt;br&gt;Existing clinical diagnostic laboratory test that is cleared or approved by the FDA</td>
</tr>
<tr>
<td>Assign a unique HCPCS code for the test; and&lt;br&gt;Publicly report the payment rate for the test.</td>
<td>Existing advanced diagnostic laboratory test</td>
<td>a laboratory test that is cleared or approved by the FDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the Secretary shall utilize a means to track such test through a mechanism such as a HCPCS code or modifier.</td>
</tr>
</tbody>
</table>

### Role for CPT

There appears to be consensus among many stakeholders that CPT codes are the applicable unique HCPCS codes for existing tests paid by Medicare (Bucket #2).

Should CPT be the Temporary HCPCS code (Bucket #1)?

What about the HCPCS Code or Modifier Requested by the Lab (Bucket #3)?
Industry concerns for CPT fulfilling PAMA coding requirement

- The requisite level of specificity for code descriptors in this section. **Will need to be MAAA-like**

- Codes will need quarterly release. **CPT will need separate cycle**

- What would be the code structure? **Will likely need alpha numeric code numbers (eg, 80X00) to handle potential large volume.**

- Is there a preference for where these codes are placed within the CPT code set? **Category I**

- ADLTs and CDLTs should not be differentiated by coding. **Good news for CPT**

- Temporary codes should be different than permanent codes? **Easier for CPT**
CPT Editorial Panel February 6, 2015

Approved:

- The creation of a Proprietary Laboratory Analysis (PLA) Section in CPT
- The creation of a Proprietary Laboratory Analysis Advisory Group to assist in the unique aspects of this section
- The creation of a new Code Change Proposal (CCP) form for use in the new PLA section
- The Editorial Panel recognized that modifications of this section would likely be warranted following CMS release of the PAMA Final Rule.

Drugs of Abuse Testing

- Drug of Abuse testing historically has become a significant industry within and alongside traditional medicine (including POCT)
- Abusive billing practices were being investigated by DoJ’s
- CPT Coding structure was not conducive to protect against abuse
- CMS created G-codes to attempt to address the issue, creating a dual coding system
- Analytical methodologies greatly advanced not incorporated into existing coding structure

SO:

- CPT created the Quantitative Drug Testing Workgroup in the summer of 2012
Quantitative Drug Testing Workgroup

• Worked diligently on the issues related to this testing
• Created an entirely new coding structure for drug testing:
  1. Presumptive Drug Class testing, separating analyses into:
     • Drug Class List A (eg, Ethanol, Opiates, Cocaine, etc)
     • Drug Class List B (eg, Acetaminophen, Meperidine, etc)

Quantitative Drug Testing Workgroup

2. Definitive Drug Class testing
   • Coding per analyte (58 separate codes for drug/classes)
3. Therapeutic Drug Assays
   • Largely unchanged from prior versions of CPT

• Editorial Panel Accepted for CPT2015
Drug Testing ... The Saga Continues!

- CMS did not accept CPT codes for payment
- Created G-codes for presumptive and definitive testing
- G-codes did not recognize multiple procedural and payment issues for providers
- Industry and Organized Medicine stakeholders met to workout a solution and pricing structure to present to CMS.
- CMS created new G-codes for 2016

Presumptive Drug Testing 2016

**G0477** Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

**G0478** any number of devices or procedures, (eg, immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

**G0479** any number of devices or procedures by instrumented chemistry analyzers (eg, immunoassay, enzyme assay, TOF, MALDI, LDLD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.
Definitive Drug Testing 2016

G0480 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.

G0481 qualitative or quantitative, all sources, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.

G0482 qualitative or quantitative, all sources, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.

G0483 qualitative or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.

CPT Drug Testing future

- Anticipate CPT adoption of G-code like language for presumptive testing in CPT 2017
- Definitive Testing G-code & CPT code disconnect remains although hopefully this can also be addressed in CPT 2017
Questions?