Lab Compliance and Test Utilization: Prepare for 2026 and beyond

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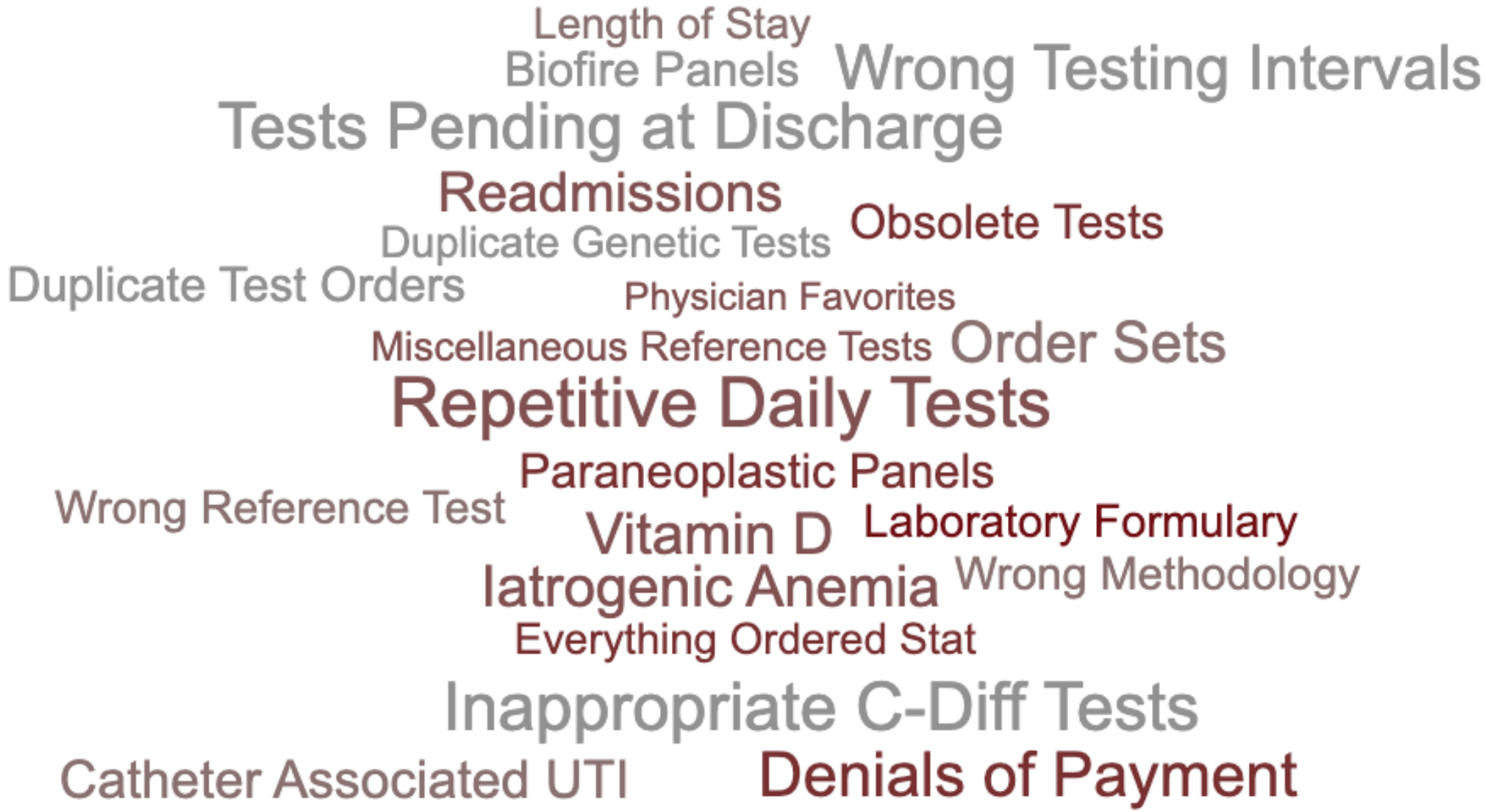
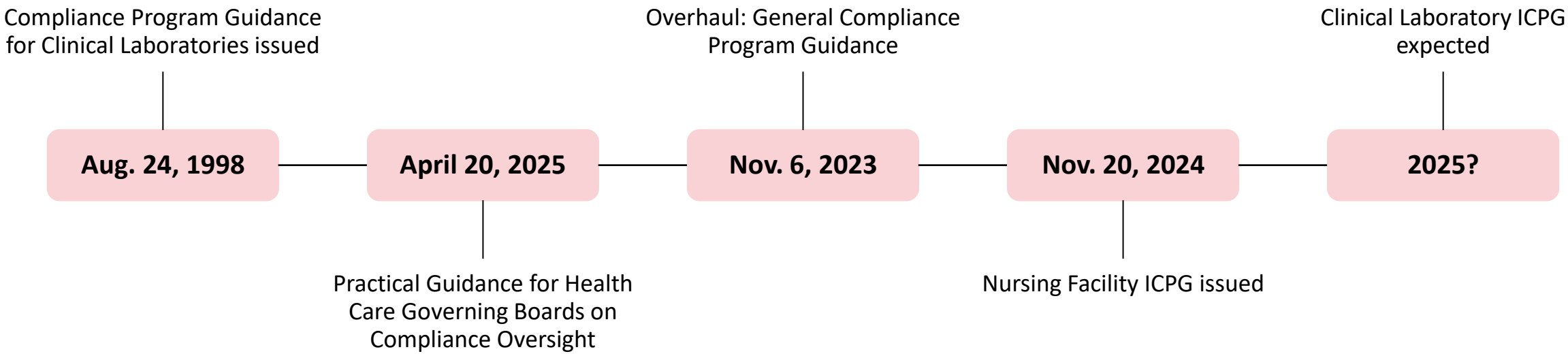
Agenda

- Evolution of OIG Guidelines 1998, 2023, 2025
- Order sets, requisitions, panels
- Physician Ordering behaviors
- OIG Resources and Processes
- Test Utilization Monitoring



GENERAL COMPLIANCE PROGRAM GUIDANCE

Timeline



Overview of General Compliance Guidance

Purpose of GCPG

GCPG provides voluntary best practices for healthcare compliance professionals to develop effective programs.

Key Compliance Elements

It emphasizes understanding federal laws, establishing strong infrastructure, and using OIG resources effectively.

Nonbinding Recommendations

The guidance offers nonbinding, risk mitigation recommendations using the term 'should' to guide healthcare entities.

Modernization and Accessibility

GCPG supports modernization in compliance and covers fraud enforcement, program elements, and organizational adaptations.

Seven Elements of Compliance Infrastructure

Written Policies and Procedures

Develop clear policies and procedures to demonstrate organizational commitment to compliance standards.

Compliance Oversight

Appoint compliance officers and committees to oversee the implementation of compliance programs effectively.

Training and Education

Provide comprehensive compliance training to employees to foster understanding and adherence.

Communication Channels

Establish open communication for reporting concerns and sharing compliance information transparently.

Monitoring and Auditing

Implement internal monitoring and auditing systems to detect and prevent compliance violations.

Enforcement and Discipline

Enforce standards through disciplinary actions to address and deter noncompliance effectively.

Response and Corrective Actions

Develop procedures to respond to offenses and initiate corrective actions promptly and effectively.

General ICPG – What is it?

Health Care Fraud Enforcement and Other Standards: Overview

Compliance Program Infrastructure: The Seven Elements

Compliance Program Adaptations for Small and Large Entities

Other Compliance Considerations

OIG Resources and Processes

Compliance Programs: DOJ's Expectations

- **Justice Manual**
- **9-28.800 - Corporate Compliance Programs**

> The adequacy of a corporation's compliance program, including its corporate culture, however, can have a direct and significant impact on the terms of any resolution with the Department. Prosecutors should evaluate a corporate compliance program as a factor in determining, *inter alia*, whether to charge the corporation, the terms of a corporate resolution, and the need for an independent compliance monitor. Prosecutors should evaluate the corporation's commitment to fostering a strong culture of compliance at all levels of the company. For example, as part of this evaluation, prosecutors should consider how the company has incentivized employee, executive, and director behavior, including through employee discipline, treatment of internal complaints of wrongdoing, and compensation plans, as part of its efforts to create an ethical and well-resourced compliance culture and organization.

Adaptations for Small and Large Entities

Small Entity Compliance

Small organizations combine roles and simplify procedures to maintain effective and manageable compliance with limited resources.

Large Entity Compliance

Larger entities implement formal structures like dedicated departments, detailed documentation, and specialized training programs.

Tailored Compliance Efforts

Compliance programs are tailored to operational scale, emphasizing integrity, accountability, and regulatory adherence.

COMPLIANCE GUIDANCE FOR CLINICAL LABORATORIES

Overview of Laboratory Compliance Guidance

Framework for Compliance

The OIG guidance provides a model framework to help laboratories comply with federal healthcare regulations effectively.

Scope of Application

Guidance applies to diverse labs including national, hospital-based, and regional facilities offering Medicare and Medicaid testing services.

Key Compliance Areas

Focus areas include fraud prevention, Anti-Kickback laws, Stark law issues, and other regulatory considerations.

Enhancing Healthcare Integrity

Adopting compliance plans helps reduce fraud and abuse, improving quality and trust in laboratory services nationwide.

Key Compliance Elements for Laboratories

Written Standards and Policies

Establish clear written standards addressing fraud risks like billing and marketing in laboratory operations.

Leadership and Oversight

Designate a chief compliance officer to oversee and manage the laboratory compliance program effectively.

Training and Education

Develop and deliver thorough education and training programs for all laboratory employees to ensure awareness.

Monitoring and Enforcement

Implement audits, evaluations, and disciplinary actions to monitor compliance and address violations promptly.

Order Sets

ED DYSPNEA (ASTHMA, COPD, PNA) ORDERS

Form No. EB-1012 Date:

DIAGNOSTIC TESTS:

Cardiology:

- ❑ EKG STAT and then every 3 hours X 2
  - ■ EKG STAT
  - ■ EKG Timed every 3 hours for 6 hours

Laboratory:

- ❑ ABG STAT
- ❑ BASIC METABOLIC PANEL STAT
- ❑ BLOOD CULTURE X 2 from 2 different sites STAT
  - ■ BLOOD CULTURE, STAT
  - ■ BLOOD CULTURE, Timed different site
- ❑ BRAIN NATRIURETIC PEPTIDE (BNP) STAT
- ❑ CBC W DIFF STAT
- ❑ CBC WO DIFF STAT
- ❑ COMPREHENSIVE METABOLIC PANEL STAT
- ❑ CULTURE, RESPIRATORY (includes Gram Stain)
- ❑ D DIMER STAT
- ❑ DIGOXIN LEVEL STAT (if on DIGOXIN)
- ❑ HEPATIC FUNCTION PANEL (LFT) STAT
- ❑ LACTIC ACID (LACTATE) BLOOD STAT
- ❑ PT / INR STAT
- ❑ PTT STAT
- ❑ Troponin STAT in ED and then every 3 hours X 2
  - ■ iSTAT Troponin and Serum Troponin STAT and then every 3 hours X 2
    - ■ Perform: iSTAT Troponin STAT
    - ■ Troponin STAT
    - ■ Troponin Timed every 3 hours for 6 hours

When iSTAT Troponin is the only test needed:

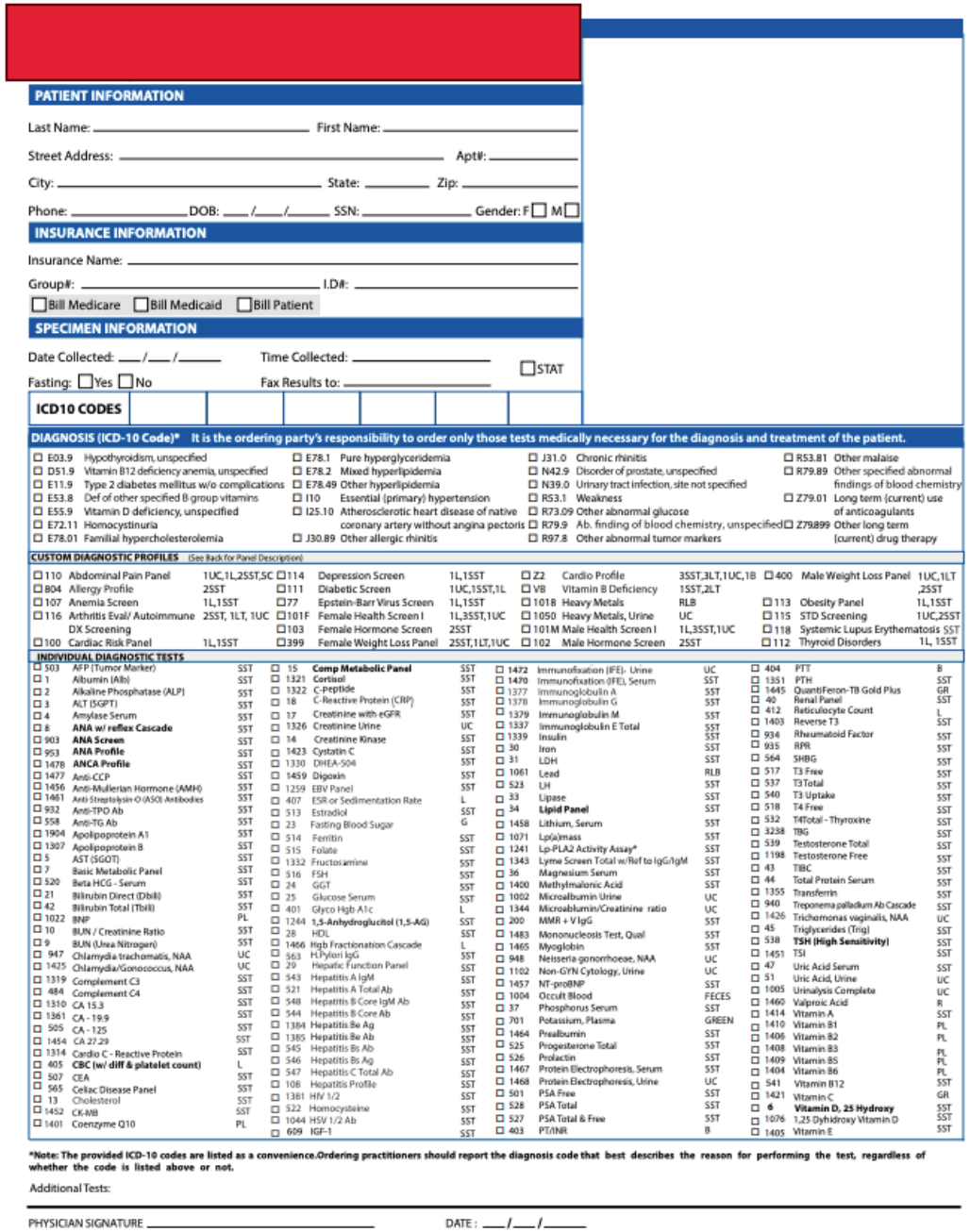
- ❑ Perform: iSTAT Troponin STAT

Poll 1:

Does your lab have input into the creation and maintenance of all order sets used in your facility*?*

- Always
- Sometimes
- Never
- Not sure

Requisitions



PATIENT INFORMATION

Last Name: _____ First Name: _____

Street Address: _____ Apt#: _____

City: _____ State: _____ Zip: _____

Phone: _____ DOB: ___/___/_____ SSN: _____ Gender: F☐ M☐

INSURANCE INFORMATION

Insurance Name: _____

Group#: _____ I.D#: _____

☐Bill Medicare ☐Bill Medicaid ☐Bill Patient

SPECIMEN INFORMATION

Date Collected: ___/___/_____ Time Collected: _____ ☐STAT

Fasting: ☐Yes ☐No Fax Results to: _____

ICD10 CODES

DIAGNOSIS (ICD-10 Code)* **It is the ordering party's responsibility to order only those tests medically necessary for the diagnosis and treatment of the patient.**

☐ E03.9	Hypothyroidism, unspecified	☐ E78.1	Pure hyperglyceridemia	☐ J31.0	Chronic rhinitis	☐ R53.81	Other malaise
☐ D51.9	Vitamin B12 deficiency anemia, unspecified	☐ E78.2	Mixed hyperlipidemia	☐ N42.9	Disorder of prostate, unspecified	☐ R79.89	Other specified abnormal findings of blood chemistry
☐ E11.9	Type 2 diabetes mellitus w/o complications	☐ E78.49	Other hyperlipidemia	☐ N39.0	Urinary tract infection, site not specified		
☐ E53.8	Def of other specified B group vitamins	☐ I10	Essential (primary) hypertension	☐ R53.1	Weakness	☐ Z79.01	Long term (current) use of anticoagulants
☐ E55.9	Vitamin D deficiency, unspecified	☐ I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris	☐ R73.09	Other abnormal glucose		
☐ E72.11	Homocystinuria			☐ R79.9	Ab. finding of blood chemistry, unspecified	☐ Z79899	Other long term (current) drug therapy
☐ E78.01	Familial hypercholesterolemia	☐ J30.89	Other allergic rhinitis	☐ R97.8	Other abnormal tumor markers		

CUSTOM DIAGNOSTIC PROFILES (See Back for Panel Description)

☐ 110	Abdominal Pain Panel	1UC,1L,2SST,SC	☐ 114	Depression Screen	1L,1SST	☐ Z2	Cardio Profile	3SST,3LT,1UC,1B	☐ 400	Male Weight Loss Panel	1UC,1LT ,2SST
☐ 804	Allergy Profile	2SST	☐ 111	Diabetic Screen	1UC,1SST,1L	☐ VB	Vitamin B Deficiency	1SST,2LT			
☐ 107	Anemia Screen	1L,1SST	☐ 77	Epstein-Barr Virus Screen	1L,1SST	☐ 1018	Heavy Metals	RLB	☐ 113	Obesity Panel	1L,1SST
☐ 116	Arthritis Eval/ Autoimmune DX Screening	2SST, 1LT, 1UC	☐ 101F	Female Health Screen I	1L,3SST,1UC	☐ 1050	Heavy Metals, Urine	UC	☐ 115	STD Screening	1UC,2SST
			☐ 103	Female Hormone Screen	2SST	☐ 101M	Male Health Screen I	1L,3SST,1UC	☐ 118	Systemic Lupus Erythematosis	SST
☐ 100	Cardiac Risk Panel	1L,1SST	☐ 399	Female Weight Loss Panel	2SST,1LT,1UC	☐ 102	Male Hormone Screen	2SST	☐ 112	Thyroid Disorders	1L, 1SST

INDIVIDUAL DIAGNOSTIC TESTS

☐ 503	AFP (Tumor Marker)	SST	☐ 15	**Comp Metabolic Panel**	SST	☐ 1472	Immunofixation (IFE), Urine	UC	☐ 404	PTT	B
☐ 1	Albumin (Alb)	SST	☐ 1321	**Cortisol**	SST	☐ 1470	Immunofixation (IFE), Serum	SST	☐ 1351	PTH	SST
☐ 2	Alkaline Phosphatase (ALP)	SST	☐ 1322	C-peptide	SST	☐ 1377	Immunoglobulin A	SST	☐ 1645	QuantiFeron-TB Gold Plus	GR
☐ 3	ALT (SGPT)	SST	☐ 18	C-Reactive Protein (CRP)	SST	☐ 1378	Immunoglobulin G	SST	☐ 40	Renal Panel	SST
☐ 4	Amylase Serum	SST	☐ 17	Creatinine with eGFR	SST	☐ 1379	Immunoglobulin M	SST	☐ 412	Reticulocyte Count	L
☐ 8	**ANA w/ reflex Cascade**	SST	☐ 1326	Creatinine Urine	UC	☐ 1337	Immunoglobulin E Total	SST	☐ 1403	Reverse T3	SST
☐ 903	**ANA Screen**	SST	☐ 14	Creatinine Kinase	SST	☐ 1339	Insulin	SST	☐ 934	Rheumatoid Factor	SST
☐ 953	**ANA Profile**	SST	☐ 1423	Cystatin C	SST	☐ 30	Iron	SST	☐ 935	RPR	SST
☐ 1478	**ANCA Profile**	SST	☐ 1330	DHEA-S04	SST	☐ 31	LDH	SST	☐ 564	SHBG	SST
☐ 1477	Anti-CCP	SST	☐ 1459	Digoxin	SST	☐ 1061	Lead	RLB	☐ 517	T3 Free	SST
☐ 1456	Anti-Mullerian Hormone (AMH)	SST	☐ 1259	EBV Panel	SST	☐ 523	LH	SST	☐ 537	T3Total	SST
☐ 1461	Anti-Streptolysin-O (ASO) Antibodies	SST	☐ 407	ESR or Sedimentation Rate	L	☐ 33	Lipase	SST	☐ 540	T3 Uptake	SST
☐ 932	Anti-TPO Ab	SST	☐ 513	Estradiol	SST	☐ 34	**Lipid Panel**	SST	☐ 518	T4 Free	SST
☐ 558	Anti-TG Ab	SST	☐ 23	Fasting Blood Sugar	G	☐ 1458	Lithium, Serum	SST	☐ 532	T4Total - Thyroxine	SST
☐ 1904	Apolipoprotein A1	SST	☐ 514	Ferritin	SST	☐ 1071	Lp(a)mass	SST	☐ 3238	TBG	SST
☐ 1307	Apolipoprotein B	SST	☐ 515	Folate	SST	☐ 1241	Lp-PLA2 Activity Assay*	SST	☐ 539	Testosterone Total	SST
☐ 5	AST (SGOT)	SST	☐ 1332	Fructosamine	SST	☐ 1343	Lyme Screen Total w/Ref to IgG/IgM	SST	☐ 1198	Testosterone Free	SST
☐ 7	Basic Metabolic Panel	SST	☐ 516	FSH	SST	☐ 36	Magnesium Serum	SST	☐ 43	TIBC	SST
☐ 520	Beta HCG - Serum	SST	☐ 24	GGT	SST	☐ 1400	Methylmalonic Acid	SST	☐ 44	Total Protein Serum	SST
☐ 21	Bilirubin Direct (Dbil)	SST	☐ 25	Glucose Serum	SST	☐ 1002	Microalbumin Urine	UC	☐ 1355	Transferrin	SST
☐ 42	Bilirubin Total (Tbil)	SST	☐ 401	Glyco Hgb A1c	L	☐ 1344	Microalbumin/Creatinine ratio	UC	☐ 940	Treponema palladium Ab Cascade	SST
☐ 1022	BNP	PL	☐ 1244	1,5-Anhydroglucitol (1,5-AG)	SST	☐ 200	MMR + V IgG	SST	☐ 1426	Trichomonas vaginalis, NAA	UC
☐ 10	BUN / Creatinine Ratio	SST	☐ 28	HDL	SST	☐ 1483	Mononucleosis Test, Qual	SST	☐ 45	Triglycerides (Trig)	SST
☐ 9	BUN (Urea Nitrogen)	SST	☐ 1466	Hgb Fractionation Cascade	L	☐ 1465	Myoglobin	SST	☐ 538	**TSH (High Sensitivity)**	SST
☐ 947	Chlamydia trachomatis, NAA	UC	☐ 563	H.Pylori IgG	SST	☐ 948	Neisseria gonorrhoeae, NAA	UC	☐ 1451	TSI	SST
☐ 1425	Chlamydia/Gonococcus, NAA	UC	☐ 29	Hepatic Function Panel	SST	☐ 1102	Non-GYN Cytology, Urine	UC	☐ 47	Uric Acid Serum	SST
☐ 1319	Complement C3	SST	☐ 543	Hepatitis A IgM	SST	☐ 1457	NT-proBNP	SST	☐ 51	Uric Acid, Urine	UC
☐ 484	Complement C4	SST	☐ 521	Hepatitis A Total Ab	SST	☐ 1004	Occult Blood	FECES	☐ 1005	Urinalysis Complete	UC
☐ 1310	CA 15.3	SST	☐ 548	Hepatitis B Core IgM Ab	SST	☐ 37	Phosphorus Serum	SST	☐ 1460	Valproic Acid	R
☐ 1361	CA - 19-9	SST	☐ 544	Hepatitis B Core Ab	SST	☐ 701	Potassium, Plasma	GREEN	☐ 1414	Vitamin A	SST
☐ 505	CA - 125	SST	☐ 1384	Hepatitis Be Ag	SST	☐ 1464	Prealbumin	SST	☐ 1410	Vitamin B1	PL
☐ 1454	CA 27.29	SST	☐ 1385	Hepatitis Be Ab	SST	☐ 525	Progesterone Total	SST	☐ 1406	Vitamin B2	PL
☐ 1314	Cardio C - Reactive Protein	SST	☐ 545	Hepatitis Bs Ab	SST	☐ 526	Prolactin	SST	☐ 1408	Vitamin B3	PL
☐ 405	**CBC (w/ diff & platelet count)**	L	☐ 546	Hepatitis Bs Ag	SST	☐ 1467	Protein Electrophoresis, Serum	SST	☐ 1409	Vitamin B5	PL
☐ 507	CEA	SST	☐ 547	Hepatitis C Total Ab	SST	☐ 1468	Protein Electrophoresis, Urine	UC	☐ 1404	Vitamin B6	PL
☐ 565	Celiac Disease Panel	SST	☐ 108	Hepatitis Profile	SST	☐ 501	PSA Free	SST	☐ 541	Vitamin B12	SST
☐ 13	Cholesterol	SST	☐ 1381	HIV 1/2	SST	☐ 528	PSA Total	SST	☐ 1421	Vitamin C	GR
☐ 1452	CK-MB	SST	☐ 522	Homocysteine	SST	☐ 527	PSA Total & Free	SST	☐ 6	**Vitamin D, 25 Hydroxy**	SST
☐ 1401	Coenzyme Q10	PL	☐ 1044	HSV 1/2 Ab	SST	☐ 403	PT/INR	B	☐ 1076	1,25 Dyhidroxy Vitamin D	SST
			☐ 609	IGF-1	SST				☐ 1405	Vitamin E	SST

***Note: The provided ICD-10 codes are listed as a convenience.Ordering practitioners should report the diagnosis code that best describes the reason for performing the test, regardless of whether the code is listed above or not.**

Additional Tests:

PHYSICIAN SIGNATURE _____ DATE : ___/___/_____

001-BL-08/25

Panels

PANEL DESCRIPTION

*Any of the tests **listed** in test combinations/panels may be ordered individually.*

100 CARDIAC RISK PANEL
BNP
Triglycerides
Cholesterol
HDL
LDL Direct
Apolipoprotein A-1 & B
hsCRP
Homocysteine
Lp-PLA2 Activity Assay*
Creatinine Kinase
Lp (a) mass

VB- Vitamin B Deficiency
Vitamin B12
Vitamin B2
Vitamin B3
Vitamin B5
Vitamin B6
Vitamin B1

101 HEALTH SCREEN I

MALE 101M
CBC
Basic Metabolic Panel
Lipid Panel
Homocysteine
Hepatic Panel
Transferrin
TIBC
Vitamin B12, Folate
TSH, T4, T3
GGT
Magnesium
Ferritin
Vitamin D - 25 OH
Uric Acid
Urinalysis Complete
PSA Total
Testosterone Total
Lp-PLA2 Activity Assay*

FEMALE 101F
CBC
Basic Metabolic Panel
Lipid Panel
Homocysteine
Hepatic Panel
Transferrin
TIBC
Vitamin B12, Folate
TSH, T4, T3
GGT
Magnesium
Ferritin
Vitamin D - 25 OH
Uric Acid
Urinalysis Complete
Lp-PLA2 Activity Assay*

102 MALE HORMONE SCREEN
Testosterone Total
Testosterone Free
Estradiol
Progesterone
DHEA S04
SHBG
Prolactin
PSA Total

103 FEMALE HORMONE SCREEN
FSH
LH
Prolactin
Progesterone
Estradiol
Testosterone Total
SHBG
DHEA S04

399 FEMALE WEIGHT LOSS PANEL
Estradiol
Progesterone
TSH
Free T4
Free T3
Total Testosterone
DHEA SO4
Glucose
Triglycerides
Total Cholesterol
LDL (low-density lipoprotein)
HDL (high-density lipoprotein)
C-reactive Protein
Liver Function
Kidney Function
Complete Blood Cell Counts
Homocysteine
Hepatitis C
Urinalysis Complete

400 MALE WEIGHT LOSS PANEL
Total Testosterone
Estradiol
DHEA SO4
TSH
Free T4
Free T3
Glucose
Triglycerides
Total Cholesterol
LDL (low-density lipoprotein)
HDL (high-density lipoprotein)
C-reactive Protein
Liver Function
Kidney Function
Complete Blood Cell Counts
PSA (prostate-specific antigen)
Homocysteine
Hepatitis C
Urinalysis Complete

118 Systemic Lupus Erythematosis Profile
ANA PROFILE, MFIA
Complement C3
Complement C4
Rheumatoid Factor

**804 ALLERGY CARE PROFILE

D1	Dermatophagoides pteronyssinus	T1	Maple	F201	Pecan Nut
D2	Dermatophagoides farinae	T22	Pecan	F202	Cashew
D70	Acarus siro	T3	Birch	F203	Pistachio
E1	Cat Dander-Epithelium	T6	Mountain Cedar	F214	Spinach
E2	Dog Epithelium	T7	Oak	F24	Shrimp
E5	Dog Dander	T8	Elm	F245	Egg
G10	Johnson Grass	W10	Lamb's Quarters	F25	Tomato
G1	Sweet Vernal Grass	W14	Rough Pigweed	F33	Orange
G2	Bermuda Grass	W18	Sheep Sorrel	F4	Wheat
G3	Orchard Grass	W1	Common Ragweed	F40	Tuna
G6	Timothy Grass	W20	Nettle	F41	Salmon
H1	House Dust—Greer	W6	Mugwort	F44	Strawberry
I1	Honey Bee Venom	W9	English Plantain	F45	Baker's Yeast
I206	American Cockroach	F1	Egg White	F47	Garlic
I6	Cockroach	F105	Chocolate	F7	Oat
K82	Latex	F13	Peanut	F75	Egg Yolk
M1	Penicillium notatum	F14	Soybean	F79	Gluten
M2	Cladosporium herbarum	F17	Hazelnut	F83	Chicken Meat
M3	Aspergillus fumigatus	F2	Milk	F9	Rice
M4	Mucor racemosus	F20	Almond	F92	Banana
M6	Alternaria tenuis				

**ADDITIONAL ALLERGENS AVAILABLE
FOR MORE INFORMATION AND ORDER
PLEASE CALL SMA LAB (877)697-6252

22 CARDIO PROFILE
Lipid Panel
Apo A1; Apo B
Lp-PLA2*
Hs-CRP
BNP
Insulin
Vitamin D-25 OH
Homocysteine
Ferritin
Folate
Magnesium, serum
Creatinine Kinase
Fibrinogen
Lp(a) mass
FFA/NEFA
MPO
Coenzyme Q10
F2-Isoprostane/Creatinine
Aspirin Works
NMR profile

1050 HEAVY METALS, URINE
Aluminum
Arsenic
Cadmium
Chromium
Cobalt
Copper
Lead
Manganese
Mercury
Thallium
Zinc

1478 ANCA Profile
Anti-MPO
ANTI-PR3
ANTI-GMB

110 ABDOMINAL PAIN PANEL
CBC (w/diff & platelet count)
Basic Metabolic Panel
Hepatic Function Panel
Amylase Serum
Lipase
Hepatitis Panel
Occult Blood, Stool Card
H.Pylori IgG
ESR or Sedimentation Rate
C-Reactive Protein (CRP)
Urinalysis Complete
(dipstick and microscopic)
CA - 19.9
AFP (Tumor Marker)
CEA

77 EPSTEIN-BARR VIRUS SCREEN
EBV VCA IgM
EBV VCA IgG
EBV to Early Antigen
EBV to Nuclear Antigen-1
ESR (Sedimentation Rate)
Syphilis Ab Cascading Reflex

111 DIABETIC SCREEN
CBC (w/diff & platelet count)
Basic Metabolic Panel
Hepatic Function Panel
Glyco Hgb A1c
Lipid Profile
Microalbumin Urine
Urinalysis Complete
(dipstick and microscopic)
Fructosamine
Glyco Mark

112 THYROID DISORDERS
CBC with differential
BMP
Hepatic Function Panel
Lipid Panel
TSH
T4 Free
TT3
Creatinine Kinase
Anti- TPO Ab
Anti- TG Ab

1018 HEAVY METALS (RLB)
Aluminum
Arsenic
Beryllium
Cadmium
Cobalt
Copper
Manganese
Molibdenum
Nickel
Lead
Antimony
Selenium
Tin
Thallium
Tungsten
Zinc
Mercury

113 OBESITY PANEL
CBC (w/diff & platelet count)
BMP
Hepatic Function Panel
TSH
Free T4
Lipid Panel
Insulin
Glyco Hgb A1c

107 ANEMIA SCREEN
CBC
Vitamin B12 & Folate
Ferritin
Methylmalonic Acid
TIBC
Reticulocyte Count

114 DEPRESSION SCREEN
CBC (w/diff & platelet count)
Basic Metabolic Panel
Hepatic Function Panel
TSH (High Sensitivity)
Vitamin B12
Folate
Vitamin D, 25 Hydroxy

115 STD SCREENING
Hepatitis Panel
HIV1/2
Syphilis Ab Cascading Reflex
HSV 1/2 Ab
CT/NG, NAA
Urine Trichomonal Infection

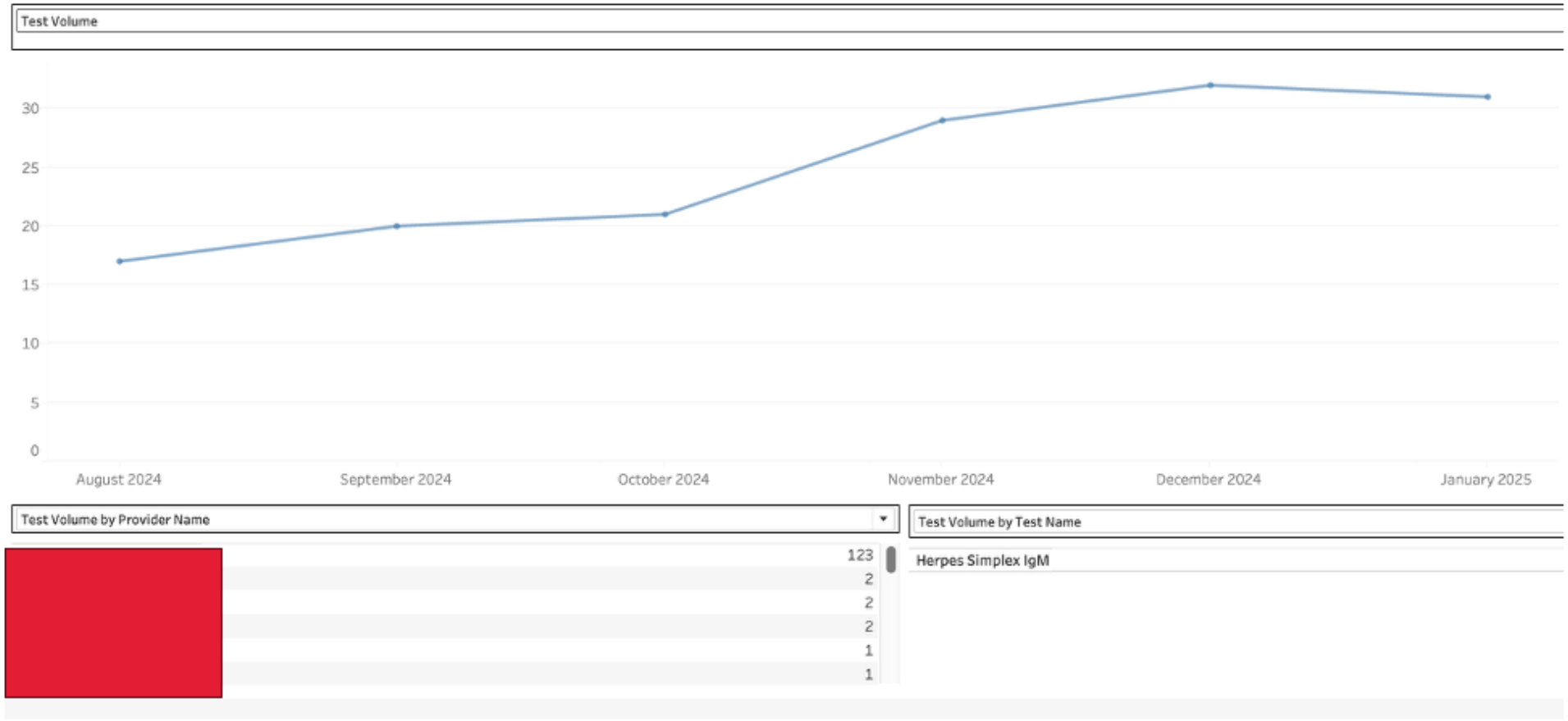
116 ARTHRITIS EVAL/ AUTOIMMUNE DX SCREENING
ESR or Sedimentation Rate
C- Reactive Protein
Rheumatoid Factor
ANA Profile
CBC (w/diff & platelet count)
Comp Metabolic Panel
Lyme Screen IgG/ IgM
Complement C3
Complement C4
Syphilis Ab Cascading Reflex
CT/NG, NAA

SPECIMEN TYPE KEY
SST = Serum Separator L = Lavender Top UC = Urine Cup R = Red Top (No Barrier) G = Grey Top WT = White Top (PPT Tube) RLB = Royal Blue SC= Stool Card PL= Plasma Lavender B=Blue Top GR=Green Top

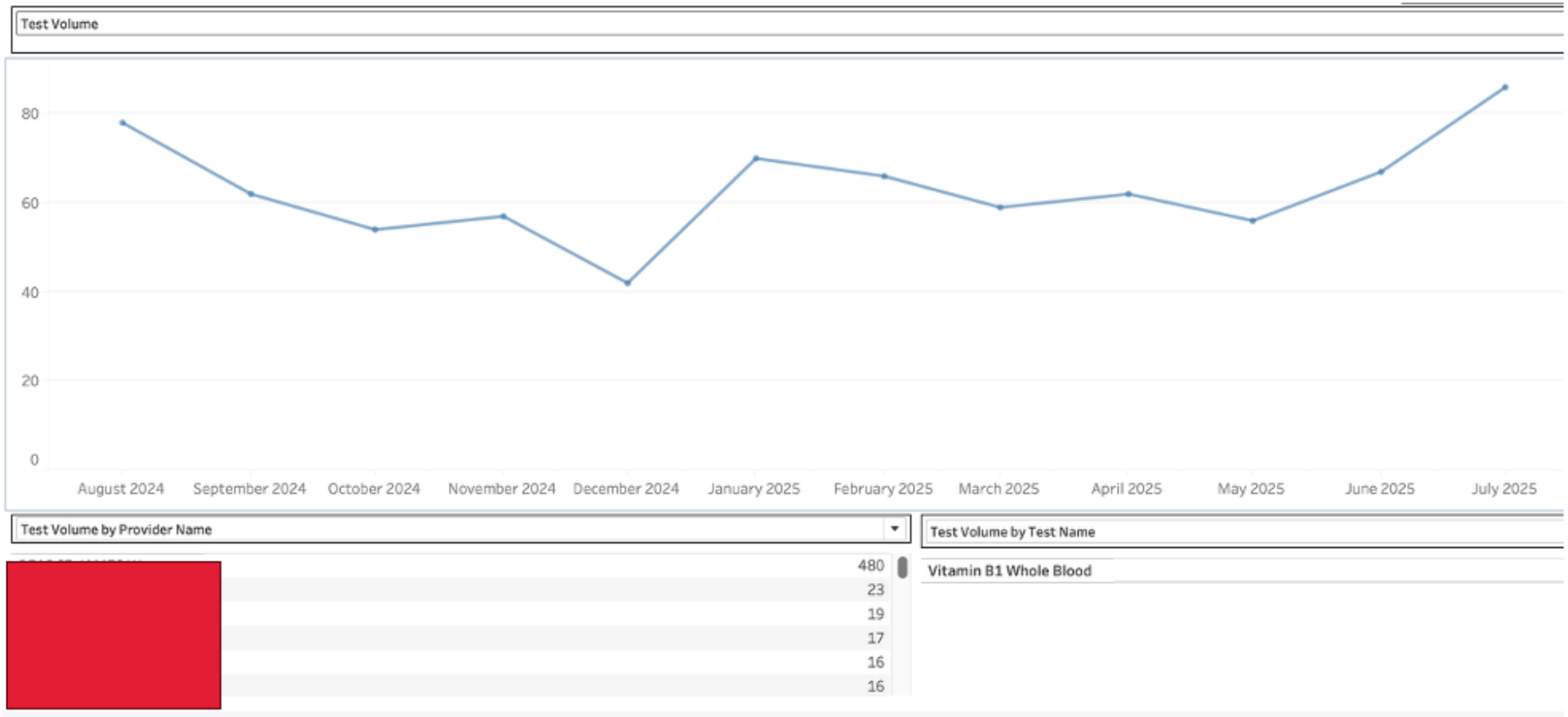
Panels

399 FEMALE WEIGHT LOSS PANEL	400 MALE WEIGHT LOSS PANEL
Estradiol	Total Testosterone
Progesterone	Estradiol
TSH	DHEA SO4
Free T4	TSH
Free T3	Free T4
Total Testosterone	Free T3
DHEA SO4	Glucose
Glucose	Triglycerides
Triglycerides	Total Cholesterol
Total Cholesterol	LDL (low-density lipoprotein)
LDL (low-density lipoprotein)	HDL (high-density lipoprotein)
HDL (high-density lipoprotein)	C-reactive Protein
C-reactive Protein	Liver Function
Liver Function	Kidney Function
Kidney Function	Complete Blood Cell Counts
Complete Blood Cell Counts	PSA (prostate-specific antigen)
Homocysteine	Homocysteine
Hepatitis C	Hepatitis C
Urinalysis Complete	Urinalysis Complete

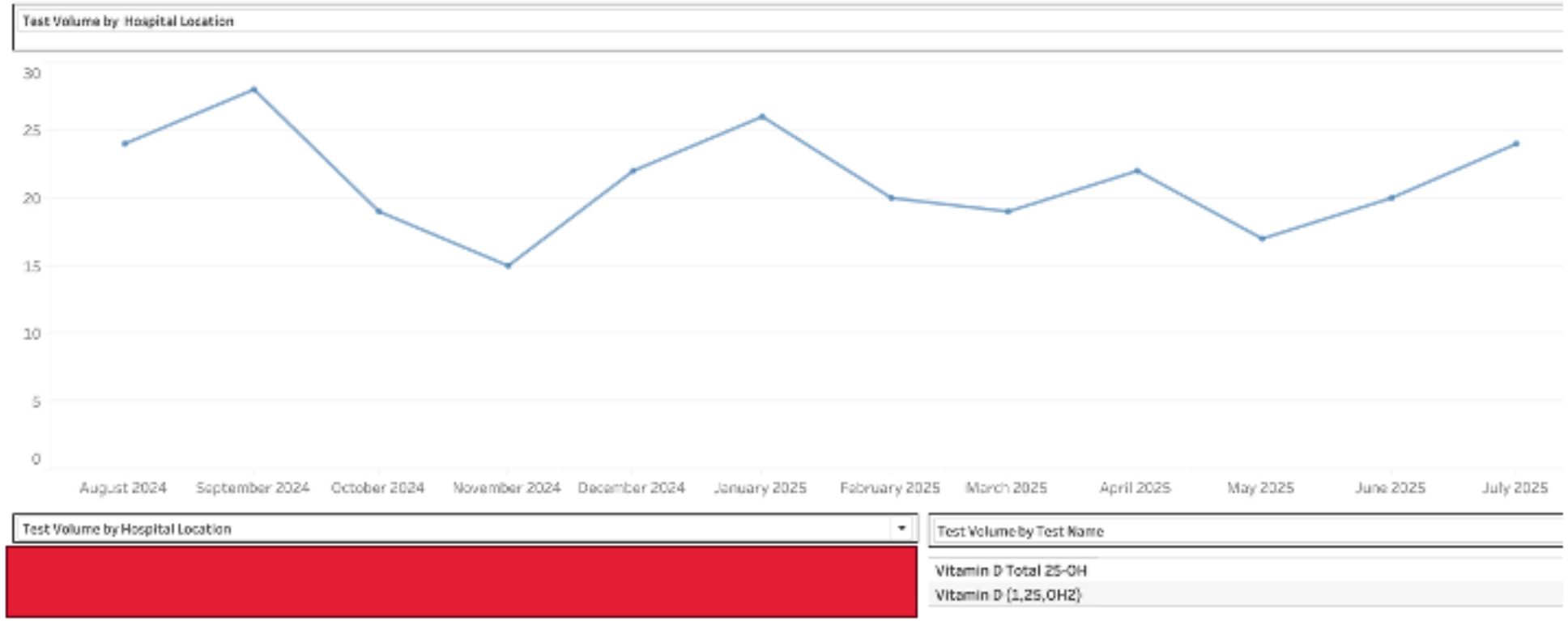
Physician Ordering Behavior



Physician Ordering Behavior



Physician Ordering Behavior (LCD)



Physician Ordering Behavior

Medicare Local Coverage Determination Policy

Coverage Policy

L37535: Vitamin D Assay Testing

CPT: 82306, 82652

Revision Effective Date: 10/01/2021

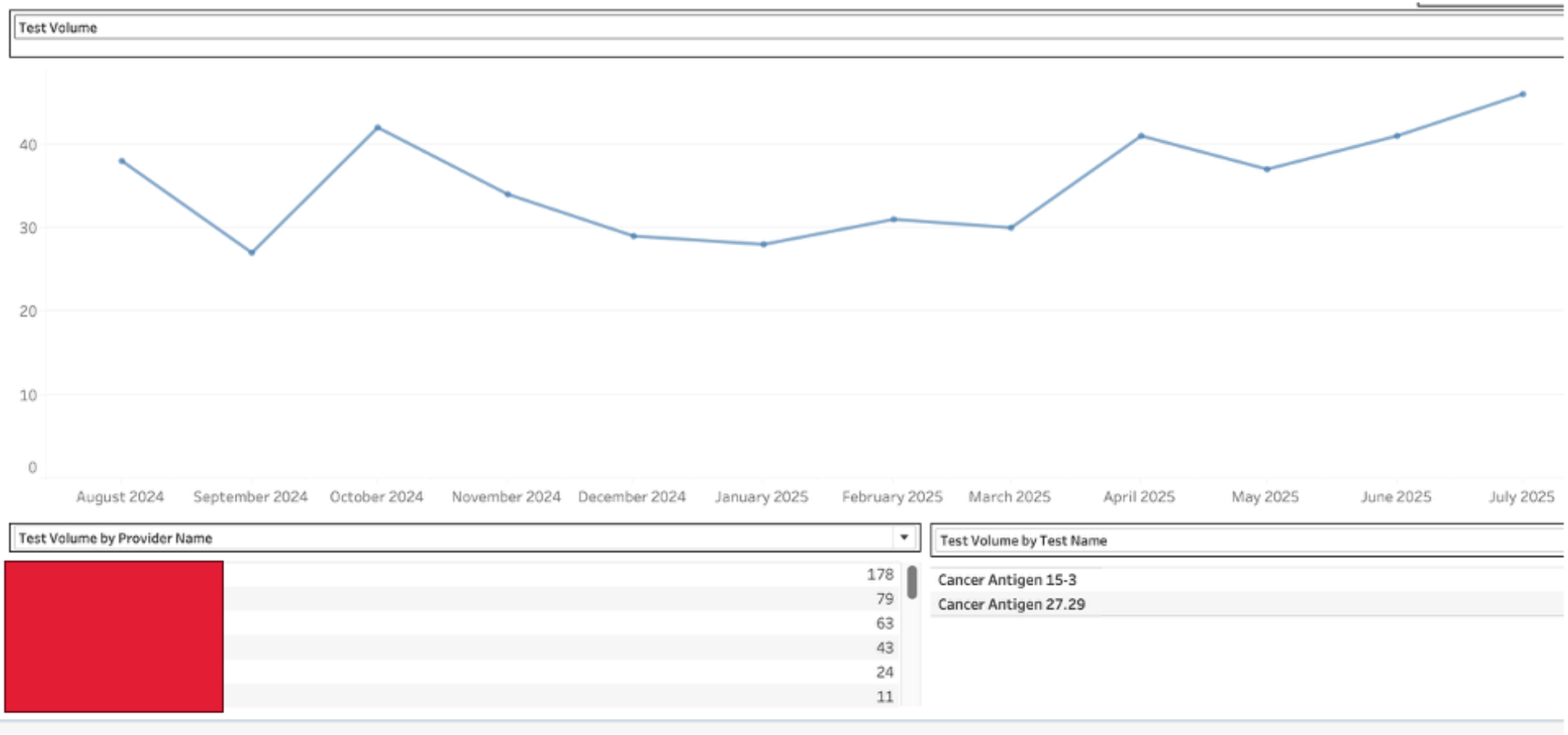
Coverage Indications, Limitations, and/or Medical Necessity

Hypovitaminosis D may result from inadequate intake, insufficient sunlight, malabsorption, liver, kidney and genetic disease. It results in the inadequate mineralization of bone. The CDC reported approximately 300,000 hip fractures, 60,000 fall-related deaths and 33 billion dollars in health care expenditures in 2014. This LCD identifies the indications and limitations of Medicare coverage for Vitamin D; 25 hydroxy and Vitamin D; 1, 25 dihydroxy laboratory assays in the medical management of patients.

Limitations

- Both assays of vitamin D need not be performed for each of the above conditions.

Physician Ordering Behavior (LCD)



Physician Ordering Behavior

Medicare National Coverage Determinations (NCD)
Coding Policy Manual and Change Report (ICD-10-CM)

190.29 - Tumor Antigen by Immunoassay CA 15-3/CA 27.29

Description

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of markers may reflect tumor size & grade. This policy specifically addresses the following tumor antigens: CA 15-3 and CA 27.29

Indications

Multiple tumor markers are available for monitoring the response of certain malignancies to therapy and assessing whether a residual tumor exists post-surgical therapy. CA 15-3 is often medically necessary to aid in the management of patients with breast cancer. Serial testing must be used in conjunction with other clinical methods for monitoring breast cancer. For monitoring, if medically necessary, use consistently either CA 15-3 or CA 27.29, not both. CA 27.29 is equivalent to CA 15-3 in its usage in management of patients with breast cancer.

OFFICE OF INSPECTOR GENERAL:

Laboratory Stewardship is Mandatory

By Andrew Fletcher, MD, MBA, CPE, CHCQM

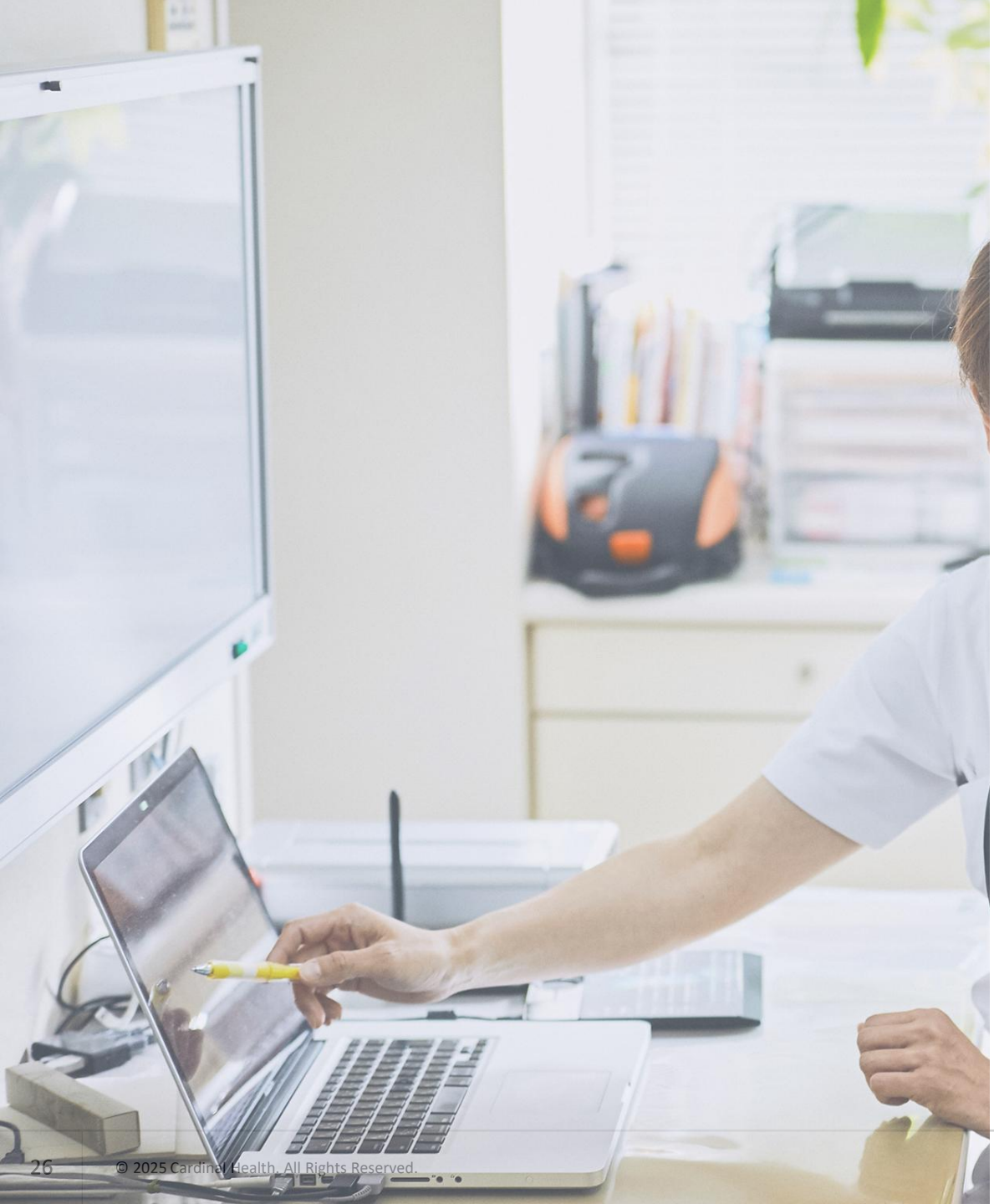
ASCP STRONGERTOGETHER

CRITICALVALUES

News for the Entire Laboratory Team

HOME ABOUT NEWS ARCHIVE ASCP

https://criticalvalues.org/news/item/2023/01/05/office-of-inspector-general-laboratory-stewardship-is-mandatory



Medical Necessity and Billing Practices

Accurate Coding Requirements

Laboratories must use correct CPT/HCPCS and ICD-9CM codes matching ordered and performed tests to ensure compliance.

Physician Documentation

Requisition forms should require ordering providers to document medical necessity including diagnosis codes for each ordered test.

Compliance and Monitoring

Laboratories should monitor test utilization data and provide notices to ordering providers to prevent fraud and billing errors.

Risk Assessments, Auditing and Monitoring

Risk Assessment

OIG Voluntary Compliance Guidance

program and should be conducted at least annually.

Tip **Entities that want to conduct compliance risk assessments more often should ensure that they dedicate the necessary time and resources for each compliance risk assessment they perform during the year.**

A formal compliance risk assessment process should pull information about risks from a variety of external and internal sources, evaluate and prioritize them, and then decide which risks to address and how to address them. The Compliance Committee should be responsible for conducting and implementing the compliance risk assessment. The Compliance Committee may find it helpful to have compliance, audit, **quality**, and risk management functions coordinate to conduct a joint risk assessment to maximize the use of entity resources and reduce the number and potential redundancy of such assessments. With this information, the Compliance Committee can work with the compliance officer to prioritize resources and develop the compliance work plan, including audits and monitoring of identified risks based on priority. (Some entity functions, such as audit, may need to perform additional risk assessments to satisfy other requirements, such as fulfilling federal grant, contract, and other award obligations under 45 CFR § 75.303, for example.)

CIA Example Requirement

F. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, [redacted] shall develop and implement a centralized annual risk assessment and internal review process to identify and address the Anti-Kickback Statute and Stark Law risks associated with Arrangements and [redacted]'s participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process.

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Corporate Integrity Agreement –

The risk assessment and internal review process shall be conducted at least annually and shall require [redacted] to: (1) identify and prioritize risks; (2) develop work plans or audit plans (as appropriate) related to the identified risk areas; (3) implement the work plans and audit plans; (4) develop corrective action plans in response to the results of any internal audits performed; and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

Know and Understand Your Data

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Entities should consider using data analytics, i.e., analyzing its data, to identify compliance risk areas. All entities, regardless of size, should have access to the data they generate, either directly or through a third party, such as a billing contractor. Data analytics efforts may range from simple to complex depending on an entity's volume of data as well as the entity's data analytics capabilities and resources.

All entities should be able to compare standard metrics of their health care operations internally to determine whether there are any outliers in any particular area of focus. Entities may use commonly available spreadsheet software to analyze their data. Other software programs that entities already use, such as billing software and electronic health records, may also have components that allow entities to analyze the data they contain. Larger entities or those with more capabilities or resources should run more sophisticated data analytics processes to assess any compliance risks presented by their operations. Analyzing data allows entities to identify possible risk areas by highlighting outliers or other data trends indicating potential noncompliance.

Between compliance risk assessments, the compliance officer should continue to scan for unidentified or new risks, by, for example, monitoring for legal and regulatory changes, enforcement actions and OIG work plan developments, and new entity acquisitions, strategies, or initiatives, and evaluating audits and investigation results. When the compliance officer or the Compliance Committee identifies a new risk, the risk should be assessed with the same methods used in the compliance risk assessment. Based on this information, the Compliance Committee can decide whether and how to address the newly identified risk.

RAT-STATS - Statistical Software

REFERENCED IN VOLUNTARY ICPG

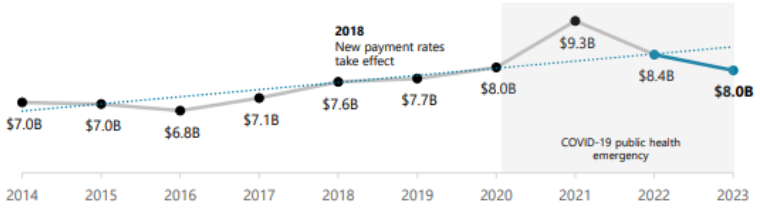
"ASSISTS THE USER IN SELECTING RANDOM SAMPLES AND ESTIMATING IMPROPER PAYMENTS."

December 2024 | OEI-09-24-00350

Total Medicare Part B Spending on Lab Tests Decreased in 2023, Driven in Part by Less Spending on COVID-19 Tests

Total Medicare Part B Laboratory Spending in 2023

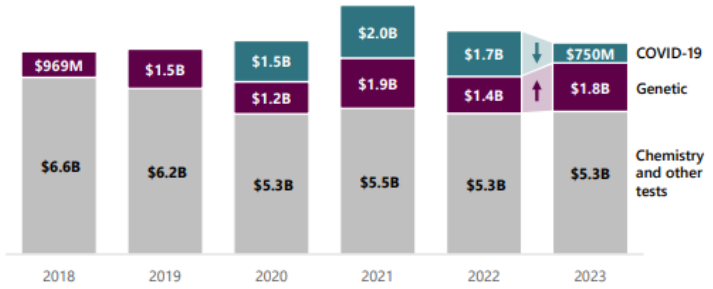
Medicare Part B spent $8.0 billion on lab tests in 2023, a 5.4 percent decrease from 2022. Over the last 10 years, lab test spending showed growth between 2014 and 2021, with peak spending during the COVID-19 public health emergency.



Source: OIG analysis of 2014-2023 Medicare Part B claims data, 2024. On January 31, 2020, the Secretary of Health and Human Services declared COVID-19 a public health emergency. The COVID-19 public health emergency declaration expired on May 11, 2023.

Total Medicare Part B Laboratory Spending by Category

After peaking in 2021, Medicare Part B spending on COVID-19 tests continued to decline, showing a sharp drop in spending in 2023. Chemistry and other tests, such as blood tests and drug tests, have accounted for the largest share of Medicare Part B's total spending on lab tests consistently since 2018 when new payment rates went into effect.[3] In addition, total spending on genetic tests has fluctuated over the last 5 years.



Source: OIG analysis of 2018-2023 Medicare Part B claims data, 2024.
Because of rounding, spending in the lab test categories may not sum to the total spending for the year.

OIG Report Cont.

Top 25 Lab Tests by Medicare Part B Spending

	Test Description (Procedure Code)	2023 payment rate	2023 volume (millions)	Volume change from 2022	2023 spending (millions)
1	Blood test, comprehensive group of blood chemicals (80053)	$10.56	38.6	0%	$405.1
2	Blood test, lipids (cholesterol and triglycerides) (80061)	$13.39	25.3	-1% ↓	$332.3
3	Blood test, thyroid stimulating hormone (TSH) (84443)	$16.80	19.2	0%	$316.0
4	**Genetic test:** Gene analysis (colorectal cancer) (81528)	$508.87	0.6	13% ↑	$301.0
5	Detection test by nucleic acid for organism, amplified probe technique (87798)	$35.09	8.5	32% ↑	$292.4
6	Complete blood cell count (red cells, white blood cells, platelets), automated (85025)	$7.77	36.5	-1% ↓	$282.3
7	Vitamin D-3 level (82306)	$29.60	8.7	-2% ↓	$250.9
8	Hemoglobin A1C level (83036)	$9.71	18.4	0%	$176.0
9	**Genetic test:** Test for detecting genes associated with cancer (81455)	$2,919.60	0.05	59% ↑	$145.2
10	Drug test(s), definitive, 22 or more drug class(es) (G0483)	$246.92	0.6	-13% ↓	$145.1
11	Testing for presence of drug, by chemistry analyzers (80307)	$62.14	2.1	-8% ↓	$129.1
12	**COVID-19 test:** Infectious agent detection by nucleic acid (DNA or RNA); severe acute (U0003)	$75.00	1.6	-83% ↓	$115.0
13	Drug test(s), definitive, 15-21 drug class(es) (G0482)	$198.74	0.6	-9% ↓	$110.5
14	**Genetic test:** Gene analysis of 55-74 genes associated with solid organ cancer in cell-free (0242U)	$5,000.00	0.02	31% ↑	$104.8
15	**COVID-19 test:** Detection test by multiplex amplified probe technique for severe acute (87637)	$142.63	0.7	**New to top 25**	$103.6
16	Parathormone (parathyroid hormone) level (83970)	$41.28	2.6	1% ↑	$103.1
17	**Genetic test:** Test for detecting genes associated with breast cancer (81519)	$3,873.00	0.03	2% ↑	$94.7
18	Cyanocobalamin (vitamin B-12) level (82607)	$15.08	6.2	5% ↑	$91.9
19	**COVID-19 test:** Respiratory infectious agent detection by RNA for severe acute respiratory (0241U)	$142.63	0.6	-1% ↓	$79.9
20	Blood test, basic group of blood chemicals (calcium, total) (80048)	$8.46	9.3	-4% ↓	$79.4
21	Drug test(s), definitive, 1-7 drug class(es) (G0480)	$114.43	0.7	-4% ↓	$77.8
22	**COVID-19 test:** Amplified DNA or RNA probe detection of severe acute respiratory syndrome (87635)	$51.31	1.5	-17% ↓	$76.4
23	PSA (prostate specific antigen) measurement, total (84153)	$18.39	4.2	0%	$76.2
24	**Genetic test:** mRNA gene expression analysis of 22 genes in prostate tumor tissue (81542)	$3,873.00	0.02	**New to top 25**	$71.7
25	Drug test(s), definitive, 8-14 drug class(es) (G0481)	$156.59	0.5	**New to top 25**	$70.5
	Total Medicare Part B spending on the top 25 lab tests in 2023: $4.0 billion				

Sources: OIG analysis of 2022–2023 spending on lab tests in Medicare Part B, 2024. Payment rates are from the 2023 CLFS. *CPT copyright*

Internal Auditing & Monitoring

1998 Guidance: Audit laboratory's compliance with laws governing kickbacks arrangements, physician self-referral prohibition, coding and billing, claim submission, medical necessity and marketing[1]

2. Auditing and Monitoring

The Compliance Committee should include in the compliance work plan a schedule of audits to be conducted based on risks identified by the annual risk assessment. The Compliance Committee also should ensure that the compliance officer has the capacity to perform or oversee additional audits based on risks identified throughout the year, for example, as part of an investigation into an overpayment that uncovers a potential systemic issue. The audits may be conducted by internal or external auditors who have expertise in Federal and State health care statutes, regulations, and Federal health care program requirements.

Tip

Medicare requires, as a condition of payment, that items and services be medically reasonable and necessary. Therefore, entities should ensure that any claims reviews and audits include a review of the medical necessity of the item or service by an appropriately credentialed clinician. Entities that do not include clinical review of medical necessity in their claims audits may fail to identify important compliance concerns relating to medical necessity.

Poll 2:

Do you currently monitor your tests on a periodic basis to review medical necessity and test utilization?

- Yes
- No
- Not sure

Healthcare Fraud – Considerations for Test Utilization

- Nature of items or services provided: Are the items and services actually needed and rendered, commercially reasonable, and necessary to achieve a legitimate business purpose?

- Federal program impact: (a) Does the remuneration have the potential to affect costs to any of the Federal health care programs or their beneficiaries? (b) Could the remuneration lead to overutilization or inappropriate utilization?

Healthcare Fraud – Considerations for Test Utilization

- Clinical decision making. (a) Does the arrangement or practice have the potential to interfere with, or skew, clinical decision making? (b) Does the arrangement or practice raise patient safety or quality of care concerns? (c) Could the payment structure lead to cherry-picking healthy patients or lemon-dropping patients with chronic or other potentially costly conditions to save on costs?

- Steering. Does the arrangement or practice raise concerns related to steering patients or health care entities to a particular item or service, or steering to a particular health care entity to provide, supply, or furnish items or services?

1998 ICPG – “Test Utilization Monitoring”

- “There are many methods by which a laboratory may determine excessive utilization of laboratory services”
  - Hire an outside consultant to analyze patterns of utilization and investigate any potential problems or aberrancies
  - Analyze test utilization data by CPT or HCPCS code for the top 30 tests performed each year
    - “We believe that if a test’s utilization grows more than 10 percent, the laboratory should undertake a reasonable inquiry to ascertain the cause of such growth”
    - Increase in utilization caused by physician ignorance or misunderstanding not acceptable

45076 **Federal Register** / Vol. 63, No. 163 / Monday, August 24, 1998 / Notices

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Laura Oliven, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 17, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–22575 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1998.

Name: National Advisory Council on the National Health Service Corps (NHSC).

Date and Time: September 9, 1998; 6:00 p.m.–9:00 p.m.; September 10–12, 1998; 9:00 a.m.–5:00 p.m.; September 13, 1998; 8:00 a.m.–11:00 a.m.

Place: Sheraton National Hotel, 900 South Orme Street, Arlington, VA 22204, (703) 521–1900.

The meeting is open to the public.

Agenda: Items will include, but not be limited to: In preparation for the year 2000 reauthorization the National Advisory Council has developed a draft position paper, ''The National Health Service Corps for the 21st Century.'' Reactions, suggestions and criticisms to this paper will be heard from public and private partners and other interested organizations on September 10–12. Copies of the draft paper will be available at the meeting. Other agenda items include updates on the NHSC program.

For further information, call Ms. Eve Morrow at (301) 594–4144.

Agenda items are subject to change as priorities dictate.

Dated: August 17, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–22574 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–15–P

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In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1998.

Name: National Advisory Committee on Rural Health.

Date and Time: September 13, 1998; 5:00 p.m.–6:30 p.m.; September 14–15, 1998; 8:30 a.m.–5:00 p.m.; September 16, 1998; 8:30 p.m.–11:30 a.m.

Place: Holiday Inn, Georgetown, 2101 Wisconsin Avenue, Washington, DC 20007. Phone: (202) 338–4600, FAX: (202) 333–6113.

The meeting is open to the public.

Agenda: A special session will be conducted on Sunday, September 13, for orientation of new members who were just appointed. Monday will include a panel discussion of ''Rural Researchers' Access to National Health Survey Data,'' a presentation and discussion of the new guidelines for designating HPSAs, and a report on ''Critical Access Hospitals.'' Tuesday will include legislative, telehealth, and regulatory updates. A presentation and discussion on the ''National Bipartisan Commission on the Future of Medicare'' will be followed by a discussion of Department interests and priorities for FY 1999. Agenda items are subject to change as priorities dictate.

Anyone requiring information regarding the subject Committee should contact Ms. Arlene A. Granderson, Office, or Rural Health Policy, Health Resources and Services Administration, Room 9–05, Parklawn Building, Rockville, Maryland 20857; telephone (301) 443–0835, FAX (301) 443–2803. Persons interested in attending any portion of the meeting or having questions regarding the meeting should contact Ms. Arlene Granderson or Ms. Lilly Snetana, Office of Rural Health Policy, Health Resources and Services Administration, telephone (301) 443–0835.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Compliance Program Guidance for Clinical Laboratories

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the OIG’s recently-issued Compliance Program Guidance for Clinical Laboratories. The OIG had previously developed and published a model compliance plan for the clinical laboratory industry on March 3, 1997. This Compliance Program Guidance for Clinical Laboratories is intended to be more consistent with compliance program guidances issued by the OIG with respect to the hospital industry and to home health agencies, and serves to clarify various aspects of the original model plan. As with previously-issued compliance program guidances, we believe that the development of this guidance for clinical laboratories will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care community.

FOR FURTHER INFORMATION CONTACT: Christine Saxonis, Office of Counsel to the Inspector General, (202) 619–2078.

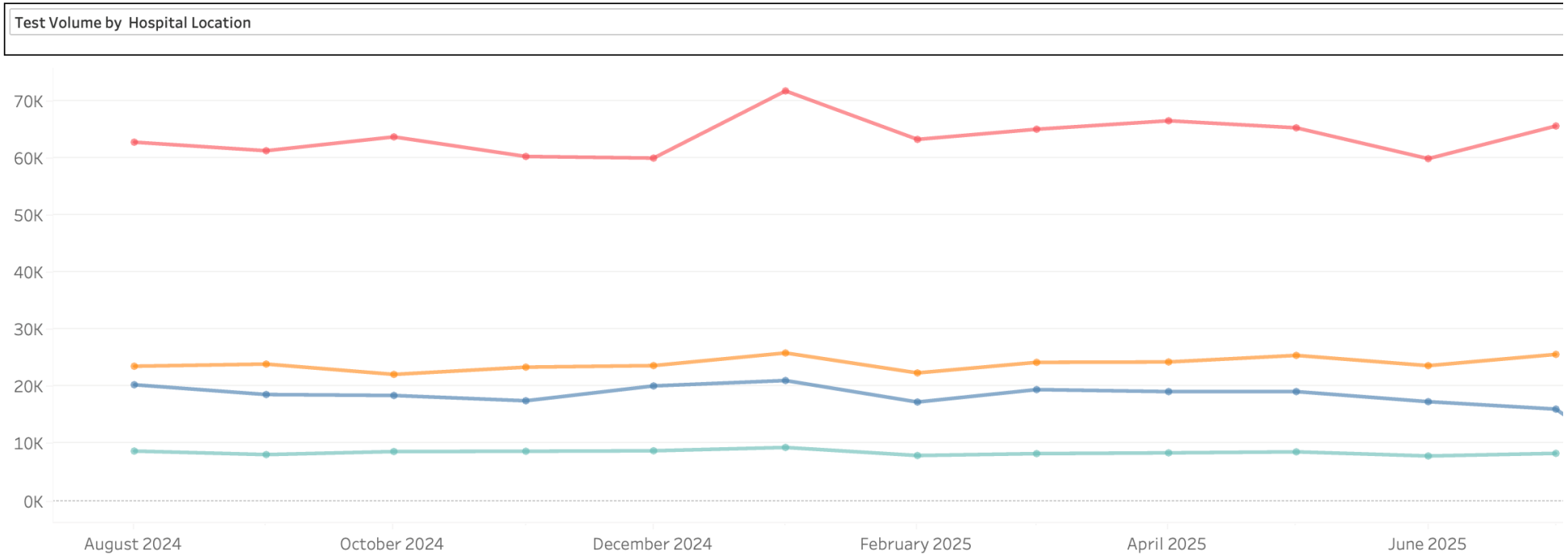
SUPPLEMENTARY INFORMATION: As part of a major initiative to engage the private health care community in combating fraud and abuse, the OIG developed and published in the **Federal Register** a model compliance plan for the clinical laboratories (62 FR 9435; March 3, 1997). The compliance plan was intended to provide clear guidance to that aspect of the clinical laboratory industry that was interested in reducing fraud and abuse within their organizations. Since that issuance, the OIG has developed and issued specific compliance program guidance for the hospital industry and for home health agencies.

This compliance program guidance is intended to refine and build on the original model guidance plan for clinical laboratories. In developing an effective compliance program, the OIG has identified 7 fundamental elements. They are:

- Implementing written policies, procedures and standards of conduct;
- Designing a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

The development of this new Compliance Program Guidance for Clinical Laboratories has been enhanced

Test Utilization Monitoring



Test Volume by Patient Type	
INPATIENT	532,884
OUTPATIENT	481,464
ER	354,013
UNKNOWN	12,315
OUTSIDE	591

Test Volume by Test Name
CBC
Comp Metabolic Panel
Basic Metabolic Panel
Magnesium
Hemoglobin A1C and EAG
Troponin T (5th Gen)

Medical Necessity & Test Utilization Monitoring

L. Testing Monitoring

[redacted] shall create and maintain a report of all orders for Testing by Ordering Providers (Testing Report). The Testing Report shall include at least the following information: (a) specific type of testing ordered, (b) patient's name, (c) Ordering Provider name (d) date the testing was ordered, and (e) reason the testing was ordered (including relevant diagnosis code). Order/requisition forms shall be modified to capture all information required for the Testing Report.

On a monthly basis, the Compliance Officer shall review the Testing Report with the Medical Director (Monthly Testing Review) to determine whether, by Ordering Provider: (a) the entries contain the required information and (b) the Ordering Provider does not exhibit patterns and practices that may be inconsistent with standards for the medical reasonableness and necessity of the testing ordered. The Compliance Officer shall prepare a written summary of the findings of each Monthly Testing Review that describes the methodology used to perform the Monthly Testing Review and the results of the Monthly Testing Review.

On a quarterly basis, the Compliance Officer, Medical Director, and Compliance Committee shall review the Testing Report to identify trends or outlier Ordering Providers for further review (Quarterly Testing Review), including but not limited to: (a) providers whose testing frequency, patterns, or practices appear to be beyond what is medically reasonable and

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Corporate Integrity Agreement – [redacted]

45076 **Federal Register** / Vol. 63, No. 163 / Monday, August 24, 1998 / Notices

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Jane M. Harrison,

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[FR Doc. 98–22574 Filed 8–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

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NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Page 45081

Reliance on Standing Orders

- Have led too often to abusive practices
- Compliance program requires the lab to periodically monitor standing orders
- Fixed term of validity and must be renewed at their expiration

Justice.gov > Office of Public Affairs > News > Press Releases > [redacted] To Pay $22 Million To Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices

This is archived content from the U.S. Department of Justice website. The information here may be outdated and links may no longer function. Please contact webmaster@usdoj.gov if you have any questions about the archive site.

PRESS RELEASE

[redacted] to Pay $22 Million to Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices

PRESS RELEASE

[redacted] Clinic Agrees to Pay $2.8 Million to Resolve Claims of Overbilling for Diagnostic Tests

Medical Necessity and Enforcement Actions

- Reference laboratory and its owners and officers entered into a settlement agreement to pay more than $1.2 million to resolve allegations that they submitted false and fraudulent claims for medically unnecessary urine drug tests. Lab accepted tests from sober homes for “residential monitoring” and submitted claims for “medically unnecessary duplicative urine drug testing”.
- “[Lab] routinely performed more expensive CBC with WBC differential tests when, in fact, medical providers had ordered less expensive CBC with no WBC differential tests and then billed federal healthcare programs for the more expensive and medically unnecessary tests.”

Key Takeaways

Questions?

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