TECHNICAL BULLETIN DECEMBER 2019

LABORATORY NOTIFICATION:
Test Launches and Changes

December 20, 2019

Dear Valued Client:

Cleveland HeartLab will be implementing changes to various tests on **Tuesday, January 28, 2020**. Highlighted in this bulletin are key changes to specified tests. Changes may include new test offerings and discontinuation of tests (**bolded** below), as well as changes to information of existing tests (eg, reference ranges, methodology, general information, etc). Additional information that is not listed remains unchanged.

Technical Bulletin December 2019 Summary – *Changes Effective January 2020*

				I. New		II. Changes to Existing													
Page #	Section	Test Name	Order Code	New Test Offering	Discontinued Test	Name Change	Clinical Significance Description	Order Code	CPT Code	NY-Approval	Patient Instructions	Specimen Collection	Stability	Rejection Criteria	Performing Lab	Methodology Description	Turnaround Time	Priority Values	Reference Range, Risk Range,
2	**Immune**	**ANA by EIA**	**C2347**				■												
2	**Immune**	**ANA by IFA Screen**	**C2344**				■												
2	**Immune**	**ANA by IFA with Reflex**	**C2500**				■												
2	**Immune**	**ANA Panel I**	**C2472**				■												
2	**Immune**	**ANA Screen, IFA, with Reflex to Titer and Pattern**	**249**	■															
3	**Immune**	**ANA Screen, IFA, with Reflex to Titer and Pattern, and Reflex to Multiplex 11 Ab Cascade**	**16814**	■															
4	**Immune**	**ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 1**	**90072**	■															
4	**Immune**	**ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 2**	**29839**	■															
5	**Immune**	**ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 3**	**19881**	■															
6	**Immune**	**Complement Component C3c**	**351**	■															
6	**Immune**	**Complement Component C4c**	**353**	■															
6	**Immune**	**Complement Component C3c and C4c**	**57048**	■															
7	**Immune**	**Complement, Total**	**618**	■															
8	**Immune**	**Centromere B Antibody**	**16088**	■															
8	**Immune**	**Chromatin Antibody**	**34088**	■															
8	**Immune**	**DNA ds Antibody**	**255**	■															
8	**Immune**	**Jo-1 Antibody**	**5810**	■															
9	**Immune**	**Ribosomal P Antibody**	**34283**	■															
9	**Immune**	**RNP Antibody**	**19887**	■															
9	**Immune**	**Scleroderma Antibody (SCL-70)**	**4942**	■															
10	**Immune**	**Sjögrens Antibody (SS-A)**	**38568**	■															
10	**Immune**	**Sjögrens Antibody (SS-B)**	**38569**	■															
11	**Immune**	**Sm Antibody**	**37923**	■															
11	**Immune**	**Sm/RNP Antibody**	**38567**	■															
11	**Immune**	**Sm and Sm/RNP Antibody**	**7448**	■															
12	**Immune**	**Gliadin (Deamidated) Antibody, IgA**	**11228**	■															
12	**Immune**	**Gliadin (Deamidated) Antibody, IgG**	**11212**	■															
13	**Immune**	**Lyme Disease Antibodies (IgG, IgM), Immunoblot**	**8593**	■															
14	Hypertension/Heart Failure	Galectin-3	C315											■					
15	Immune	Immunoglobulin A (IgA)	C1362																■
16	Immune	Sjögren's Antibodies (SS-A; SS-B)	C1388													■	■		■
17	General Chemistry	Urinalysis, Macroscopic	1381																■
17	General Chemistry	Urinalysis, Microscopic	1390																■
18	Lipoprotein Fractionation	HDL2b	1342											■					
18	Lipoprotein Fractionation	sd-LDL	1341											■					
19	Vitamins/Supplements	Folate, Serum	C258												■				

I. New Test Offerings and Discontinuations – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will **discontinue** the following Antinuclear Antibody (ANA) tests:

1. ANA by EIA (Order Code C2347)
2. ANA by IFA Screen (Order Code C2344)
3. ANA by IFA with Reflex (Order Code C2500)
4. ANA Panel I (Order Code C2472)

Please Note:
Discontinuation of these tests may impact certain custom profiles. If you would like to make changes to custom profiles, please contact your Sales Representative.

We will begin offering several new ANA panels and independent test options for enhanced clinical utility in autoimmune disease testing.

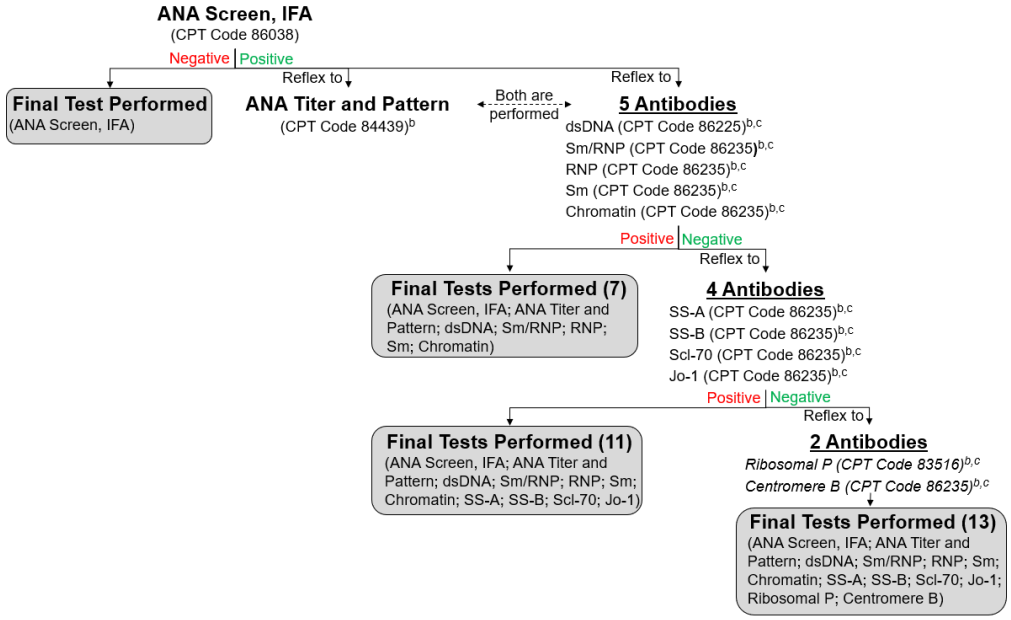
On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **ANA Screen, IFA, with Reflex to Titer and Pattern.** The information below summarizes key components for this test. **This test will replace ANA by IFA Screen (C2344) in existing custom profiles.**

	Test Name[a]	ANA Screen, IFA, with Reflex to Titer and Pattern
Ordering	Order Code	249
	CPT Code[b]	ANA Screen, IFA (86038) *If Reflexed:* ANA Titer and Pattern (86039)[c]
	NY-Approval	Yes
	Tests Included	ANA Screen, IFA *If Reflexed:* ANA Titer and Pattern[c]
	Clinical Significance	Antinuclear antibodies are associated with rheumatic diseases including Systemic Lupus Erythematous (SLE), mixed connective tissue disease, Sjögren's Syndrome, scleroderma, polymyositis, CREST syndrome, and neurologic SLE.
	Patient Instructions	Fasting is not required
Processing	Specimen/Tube Type	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated
	Volume	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Microbial contamination
Analysis	Performing Laboratory	Quest Diagnostics – Chantilly, VA
	Methodology	Immunofluorescence Assay (IFA)
	Turnaround Time	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Analyte* — *Interpretation* ANA Screen — Negative ANA Titer <1:40 — Negative 1:40-1:80 — Low antibody level >1:80 — Elevated antibody level

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.
[c] **Reflex testing is performed at an additional charge.**

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **ANA Screen, IFA, Reflex Titer/Pattern, and Reflex to Multiplex 11 Ab Cascade.** The information below summarizes key components for this test.

	Test Name[a]	**ANA Screen, IFA, Reflex Titer/Pattern, and Reflex to Multiplex 11 Ab Cascade**
Ordering	**Order Code**	16814
	NY-Approval	Yes
	CPT Code[b]	ANA Screen, IFA (86038) *If reflexed,* ANA Titer and Pattern (86039); dsDNA (86225); Sm/RNP (86235), RNP (86235); Sm (86235); Chromatin (86235); SS-A (86235); SS-B (86235); Scl-70 (86235); Jo-1 (86235);Ribosomal P (83516); and Centromere B (86235) antibodies may be performed at an additional charge.[c]
	Tests Included	ANA Screen, IFA, Reflex Titer/Pattern, and Reflex to Multiplex 11 Ab Cascade begins with an ANA Screen, IFA.  Please note the cascade stops upon the first positive antibody result(s) found in a group ("Positive" pathway in red text) and an interpretive message is applied based on this information. It is possible that antibodies in subsequent groups are also positive, but will not be added, billed, or reported.
	Clinical Significance	Antinuclear antibodies are associated with rheumatic diseases including Systemic Lupus Erythematous (SLE), mixed connective tissue disease, Sjögren's Syndrome, scleroderma, polymyositis, CREST syndrome, and neurologic SLE.
	Patient Instructions	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated
	Volume	4.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Microbial contamination 8. Gross icterus
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA
	Methodology	Refer to individual tests
	Turnaround Time	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).

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[c] **Reflex testing is performed at an additional charge.**

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **three ANA Screen, IFA with Reflex to Titer and Pattern/Lupus Panel** test options**.** The information below summarizes key components for these tests.

	Test Name[a]	ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 1	ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 2
Ordering	**Order Code**	90072	29839
	CPT Code[b]	ANA Screen, IFA (86038) If ANA Screen, IFA is positive, ANA Titer and Pattern (86039); DNA (ds) Antibody (86225); Sm Antibody (75124); and Chromatin (Nucleosomal) Antibody (86235) are performed at an additional charge.[c]	ANA Screen, IFA (86038) DNA (ds) Antibody (86225) Scleroderma Antibodies (SCL-70) (86235) Sm Antibody (86235) Sm/RNP Antibody (86235) Sjögren's Antibody (SS-A) (86235) Sjögren's Antibody (SS-B) (86235) If ANA Screen, IFA is positive, then ANA Titer and Pattern (86039) are performed at an additional charge.[c]
	NY-Approval	Yes	Yes
	Tests Included	ANA Screen, IFA *If Reflexed,*[c] ANA Titer and Pattern; DNA (ds) Antibody); Sm Antibody; Chromatin (Nucleosomal) Antibody	ANA Screen, IFA; DNA (ds) Antibody); Scleroderma Antibodies (SCL-70); Sm Antibody; Sm/RNP Antibody; Sjögren's Antibody (SS-A); Sjögren's Antibody (SS-B) *If Reflexed,*[c] ANA Titer and Pattern
	Clinical Significance	Antinuclear antibodies are associated with rheumatic diseases including Systemic Lupus Erythematous (SLE), mixed connective tissue disease, Sjögren's Syndrome, scleroderma, polymyositis, CREST syndrome, and neurologic SLE.	Antinuclear antibodies are associated with rheumatic diseases including Systemic Lupus Erythematous (SLE), mixed connective tissue disease, Sjögren's Syndrome, scleroderma, polymyositis, CREST syndrome, and neurologic SLE.
	Patient Instructions	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated
	Volume	2.0 mL	4.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus 8. Microbial contamination	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus 8. Microbial contamination
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Refer to individual tests	Refer to individual tests
	Turnaround Time	2-3 Days	2-3 Days
	Reference Ranges; Risk Ranges; Priority Values	Refer to Reference Ranges provided for individual tests	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed
[c] **Reflex testing is performed at an additional charge.**

I. New Test Offerings – Immune

The information below summarizes key components for this test.

	Test Name[a]	**ANA Screen, IFA, with Reflex to Titer and Pattern/Lupus Panel 3**
Ordering	**Order Code**	19881
	CPT Code[b]	ANA Screen, IFA (86038) DNA (ds) Antibody (86225) Sjögren's Antibody (SS-A) (86235) Sjögren's Antibody (SS-B) (86235) Sm Antibody (86235) RNP Antibody (86235) Chromatin (Nucleosomal) Antibody (86235) Complement Component C3c (86160) Complement Component C4c (86160) Complement, Total (CH50) (86162) If ANA Screen, IFA is positive, then ANA Titer and Pattern (86039) are performed at an additional charge.[c]
	NY-Approval	Yes
	Tests Included	ANA Screen, IFA; DNA (ds) Antibody; Sjögren's Antibody (SS-A); Sjögren's Antibody (SS-B); Sm Antibody; RNP Antibody; Chromatin (Nucleosomal) Antibody; Complement Component C3c; Complement Component C4c; Complement, Total (CH50) *If Reflexed,*[c] ANA Titer and Pattern
	Clinical Significance	Antinuclear antibodies are associated with rheumatic diseases including Systemic Lupus Erythematous (SLE), mixed connective tissue disease, Sjögren's Syndrome, scleroderma, polymyositis, CREST syndrome, and neurologic SLE.
	Patient Instructions	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	**Frozen (on Dry Ice)**
	Volume	4.0 mL (1.0 mL collected in each of **four separate tubes**)
	Stability	*Ambient:* Unacceptable *Refrigerated:* Unacceptable *Frozen:* 21 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Specimen received thawed 3. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus 8. Microbial contamination
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA
	Methodology	Refer to individual tests
	Turnaround Time	2-3 Days
	Reference Ranges; Risk Ranges; Priority Values	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.
[c] **Reflex testing is performed at an additional charge.**

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Complement Component C3c	Complement Component C4c	Complement Component C3c and C4c
Ordering	**Order Code**	351	353	57048
	CPT Code[b]	86160	86160	86160, 86160
	NY-Approval	Yes	Yes	Yes
	Tests Included	Complement Component C3c	Complement Component C4c	Complement Component C3c Complement Component C4c
	Clinical Significance	Decreased C3 may be associated with acute glomerulonephritis, membranoproliferative glomerulonephritis, immune complex disease, active systemic lupus erythematosus, and generalized autoimmune processes.	Decreased C4 levels are associated with acute systemic lupus erythematosus, glomerulonephritis, immune complex disease, cryoglobulinemia, congenital C4 deficiency, and generalized autoimmune disease	Decreased concentrations of both C3 and C4 suggest activation of the classical pathway, whereas decreased concentration of just C3 suggests activation of the alternative pathway. Both complement factors may be used to monitor activity of patients with systemic lupus erythematosus (SLE) and immune complex-induced vasculitis.
	Patient Instructions	Fasting is not required	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL	1.0 mL
	Stability	*Ambient:* Unacceptable *Refrigerated:* 4 Days *Frozen:* 21 Days	*Ambient:* Unacceptable *Refrigerated:* 4 Days *Frozen:* 21 Days	*Ambient:* Unacceptable *Refrigerated:* 4 Days *Frozen:* 21 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Specimen received at room temperature	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Specimen received at room temperature	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Specimen received at room temperature
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoturbidimetric Assay	Immunoturbidimetric Assay	Immunoturbidimetric Assay
	Turnaround Time	2-3 Days	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Age (Years)* / *Male (mg/dL)* / *Female (mg/dL)* <1 / Not established / Not established 1-14 / 80-170 / 82-173 15-80 / 82-185 / 83-193 ≥81 / Not established / Not established	Reference Range: *Age (Years)* / *Male (mg/dL)* / *Female (mg/dL)* <1 / Not established / Not established 1-14 / 14-44 / 13-46 15-80 / 15-53 / 15-57 ≥81 / Not established / Not established	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
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I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Complement, Total (CH50)
Ordering	**Order Code**	618
	CPT Code[b]	86162
	NY-Approval	Yes
	Tests Included	Complement, Total (CH50)
	Clinical Significance	CH50 is a screening test for total complement activity. Levels of complement may be depressed in genetic deficiency, liver disease, chronic glomerulonephritis, rheumatoid arthritis, hemolytic anemias, graft rejection, systemic lupus erythematosus, acute glomerulonephritis, subacute bacterial endocarditis, and cryoglobulinemia. Elevated complement may be found in acute inflammatory conditions, leukemia, Hodgkin's Disease, sarcoma, and Behcet's Disease.
	Patient Instructions	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Red-Top Tube (without Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Serum Separator Tube (SST; Gel Barrier)
	Collection Instructions	Centrifuge serum specimen within 1 hour of collection. Immediately pipette serum into sterile, plastic, screw-capped vial(s) and freeze solid at -20°C or lower. Do not allow samples to thaw. **With multiple tests, submit a separate tube for each test.** Do not submit sample in a glass tube.
	Transport Temperature	**Frozen (on Dry Ice)**
	Volume	1.0 mL
	Stability	*Ambient:* Unacceptable *Refrigerated:* Unacceptable *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Lipemia 7. Specimen received thawed
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA
	Methodology	Liposome
	Turnaround Time	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Age* | *Sex* | *Complement, Total (U/mL)* All Ages | Males & Females | 31-60

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
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I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Centromere B Antibody	Chromatin (Nucleosomal) Antibody	DNA (ds) Antibody	Jo-1 Antibody
Ordering	**Order Code**	16088	34088	255	5810
	CPT Code[b]	86235	86235	86225	86235
	NY-Approval	Yes	Yes	Yes	Yes
	Tests Included	Centromere B Antibody	Chromatin (Nucleosomal) Antibody	DNA (ds) Antibody	Jo-1 Antibody
	Clinical Significance	Centromere B Antibody is diagnostic for the form of scleroderma known as CREST (calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia).	Chromatin Antibody plays a central role in the autoimmune response in systemic lupus erythematosus (SLE). Approximately 90% of patients with SLE have sera that will exhibit reactivity to nucleosomes.	dsDNA Antibody is detected in patients with active systemic lupus erythematosus (SLE) and approximately 20% of patients with Mixed Connective Tissue Disease.	Jo-1 Antobody occurs most frequently (31%) in patients with polymyositis, but has also been found in patients with dermatomyositis, and the polymyositis/scleroderma "overlap syndrome" (PM/SCL) or polymyositis/systemic lupus erythematosus "overlap syndrome" (PM/SLE).
	Patient Instructions	Fasting is not required	Fasting is not required	Fasting is not required	Fasting is not required
Processing	**Specimen/ Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL	1.0 mL	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoassay (IA)	Immunoassay (IA)	Immunoassay (IA)	Immunoassay (IA)
	Turnaround Time	2-3 Days	2-3 Days	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Centromere B Antibody* – *Interpretation* <1.0 AI – Negative	Reference Range: *Chromatin Antibody* – *Interpretation* <1.0 AI – Negative	Reference Range: *DNA (ds) Antibody* – *Interpretation* ≤4.0 IU/mL – Negative 5-9 IU/mL – Intermediate ≥10 IU/mL – Positive	Reference Range: *Jo-1 Antibody* – *Interpretation* <1.0 AI – Negative

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).

[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Ribosomal P Antibody	RNP Antibody	Scleroderma Antibody (SCL-70)
Ordering	**Order Code**	34283	19887	4942
	CPT Code[b]	83516	86235	86235
	NY-Approval	Yes	Yes	Yes
	Tests Included	Ribosomal P Antibody	RNP Antibody	Scleroderma Antibody (SCL-70)
	Clinical Significance	Ribosomal P Antibody is present in 5-10% of patients with systemic lupus erythematosus (SLE).	RNP Antibodies have been associated with Mixed Connective Tissue disease.	Scleroderma Antibody (Scl-70) is present in approximately 40% of patients with progressive systemic sclerosis (PSS).
	Patient Instructions	Fasting is not required	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoassay (IA)	Immunoassay (IA)	Immunoassay (IA)
	Turnaround Time	2-3 Days	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Ribosomal P Antibody* | *Interpretation* <1.0 AI | Negative	Reference Range: *RNP Antibody* | *Interpretation* <1.0 AI | Negative	Reference Range: *SCL-70 Antibody* | *Interpretation* <1.0 AI | Negative

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Sjögren's Antibody (SS-A)	Sjögren's Antibody (SS-B)
Ordering	**Order Code**	38568	38569
	CPT Code[b]	86235	86235
	NY-Approval	Yes	Yes
	Tests Included	SS-A Antibody	SS-B Antibody
	Clinical Significance	Sjögren's Antibodies (SS-A and SS-B) are associated with Sjögren's Syndrome. The presence of both antibodies (SS-A and SS-B) strengthen the diagnosis of Sjogren's Syndrome and conveys prognostic information.	Sjögren's Antibodies (SS-A and SS-B) are associated with Sjögren's Syndrome. The presence of both antibodies (SS-A and SS-B) strengthen the diagnosis of Sjogren's Syndrome and conveys prognostic information.
	Patient Instructions	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoassay (IA)	Immunoassay (IA)
	Turnaround Time	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *SS-A Antibody* | *Interpretation* <1.0 AI | Negative	Reference Range: *SS-B Antibody* | *Interpretation* <1.0 AI | Negative

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

I. New Test Offerings – Immune

On **Tuesday, January 28, 2019** Cleveland HeartLab will begin offering **multiple new Immune test options.** The information below summarizes key components for these tests.

	Test Name[a]	Sm Antibody	Sm/RNP Antibody	Sm and Sm/RNP Antibody
Ordering	**Order Code**	37923	38567	7448
	CPT Code[b]	86235 (Sm Antibody)	86235 (Sm/RNP Antibody)	86235 (Sm Antibody) 86235 (Sm/RNP Antibody)
	NY-Approval	Yes	Yes	Yes
	Tests Included	Sm Antibody	Sm/RNP Antibody	Sm Antibody; Sm/RNP Antibody
	Clinical Significance	Smith Antibody (Sm) is highly specific for systemic lupus erythematosus (SLE). Smith Antibody is also detected in approximately 15-20% of patients with SLE. Smith Antibody is detected in more than half of young African American women with SLE.	Smith (Sm)/U1-RNP Antibody is detected in patients with mixed connective tissue disease (having features of systemic lupus erythematosus (SLE), scleroderma, and polymyositis).	Antibodies to Sm are highly specific for systemic lupus erythematosus (SLE) and when present are considered a marker antibody. However, these antibodies are found in only 20% of patients with SLE. RNP antibodies (also known as anti-U1 or ribonucleoprotein antibodies) are found in 45% of SLE patients but are also observed in numerous other disease states such as Sjogren's syndrome, scleroderma and polymyositis. Elevated levels to RNP are seen in mixed connective tissue disease. In SLE, RNP antibodies have been associated with a relatively benign disease course with lower incidence of renal and central nervous system involvement. Patients may be considered positive for RNP antibodies when the RNP antibody result is significantly higher than the SM antibody result.
	Patient Instructions	Fasting is not required	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia 7. Gross icterus
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoassay (IA)	Immunoassay (IA)	Immunoassay (IA)
	Turnaround Time	2-3 Days	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Sm Antibody* | *Interpretation* <1.0 AI | Negative	Reference Range: *Sm/RNP Antibody* | *Interpretation* <1.0 AI | Negative	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

I. New Test Offerings – Immune

On **Tuesday, January 28, 2020** Cleveland HeartLab will begin offering **two individual Gliadin (Deamidated) Antibody** test options**.** The information below summarizes key components for these tests. These tests are also available within the Gliadin (Deamidated Peptide) Antibody (IgG, IgA) test (Order Code C1496).

	Test Name[a]	Gliadin (Deamidated) Antibody, IgA	Gliadin (Deamidated) Antibody, IgG
Ordering	**Order Code**	11228	11212
	CPT Code[b]	83516	83516
	NY-Approval	Yes	Yes
	Tests Included	Gliadin (Deamidated) Antibody, IgA	Gliadin (Deamidated) Antibody, IgG
	Clinical Significance	Detection of antibodies to gliadin, one of the major protein components of gluten, is a sensitive assay useful in diagnosing celiac disease. However, gliadin antibodies may be found in Individuals without celiac disease; thus, gliadin antibody assays are less specific than assays measuring antibodies to endomysium and transglutaminase. Recent work has revealed that gliadin-reactive antibodies from celiac patients bind to a very limited number of specific epitopes on the gliadin molecule. Further, deamidation of gliadin results in enhanced binding of gliadin antibodies. Based on this information, assay using deamidated gliadin peptides bearing the celiac-specific epitopes have much higher diagnostic accuracy for celiac disease when compared to standard gliadin antibody assays.	Detection of antibodies to gliadin, one of the major protein components of gluten, is a sensitive assay useful in diagnosing celiac disease. However, gliadin antibodies may be found in Individuals without celiac disease; thus, gliadin antibody assays are less specific than assays measuring antibodies to endomysium and transglutaminase. Recent work has revealed that gliadin-reactive antibodies from celiac patients bind to a very limited number of specific epitopes on the gliadin molecule. Further, deamidation of gliadin results in enhanced binding of gliadin antibodies. Based on this information, assay using deamidated gliadin peptides bearing the celiac-specific epitopes have much higher diagnostic accuracy for celiac disease when compared to standard gliadin antibody assays.
	Patient Instructions	Fasting is not required	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; with Gel Barrier)	Serum, Serum Separator Tube (SST; with Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red Top Tube (without Gel Barrier)	Serum, Red Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated	Refrigerated
	Volume	1.0 mL	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia	1. Specimen other than Preferred 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia
Analysis	**Performing Laboratory**	Quest Diagnostics – Chantilly, VA	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoassay (IA)	Immunoassay (IA)
	Turnaround Time	2-3 Days	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Range* – *Interpretation* <20 Units – Antibody Not Detected ≥20 Units – Antibody Detected	Reference Range: *Range* – *Interpretation* <20 Units – Antibody Not Detected ≥20 Units – Antibody Detected

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

I. New Test Offering– Immune

On Tuesday, January 28, 2020 Cleveland HeartLab, Inc. will begin offering the **Lyme Disease Antibodies (IgG, IgM), Immunoblot** test. The information below summarizes key components for this test. This is also currently available as a reflex test for Lyme Disease Antibodies with Reflex to Blot (Order Code C1473).[a]

	Test Name[b]	Lyme Disease Antibodies (IgG, IgM), Immunoblot
Ordering	Order Code	8593
	NY-Approval	Yes
	CPT Code[c]	86617 (x2)
	Tests Included	Lyme Disease Ab (IgG), Blot Lyme Disease Ab (IgM), Blot
	Clinical Significance	Lyme disease is transmitted by a tick vector carrying *Borrelia burgdorferi*. Immunoblot testing qualitatively examines, with high specificity, antibodies in a patient's specimen. Immunoblot testing is appropriate for confirming a detected EIA or IFA test result.
	Patient Instructions	Fasting is not required
Processing	Specimen/Tube Type	Serum, Red-Top Tube (without Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Serum Separator Tube (SST; Gel Barrier)
	Transport Temperature	Refrigerated
	Volume	1.0 mL
	Stability	*Ambient:* 7 Days *Refrigerated:* 14 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia
Analysis	Performing Laboratory	Quest Diagnostics – Chantilly, VA
	Methodology	Immunoblot
	Turnaround Time	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Analyte* | *Interpretation* Lyme Disease Ab (IgG), Blot | Negative Lyme Disease Ab (IgM), Blot | Negative

[c] Reflex testing is performed at an additional charge.

[b] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).

[c] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – Hypertension/Heart Failure

On Tuesday, January 28, 2020 Cleveland HeartLab, Inc. will incorporate the following changes for the **Galactin-3** test, which are **bolded** in the table below. The primary change involves **specimen processing**.

	Test Name[a]	**Galectin-3**
Ordering	**Order Code**	C315
	NY-Approval	Yes
	CPT Code[b]	82777
	Tests Included	Galectin-3
	Clinical Significance	A galectin-3 test may be ordered for the identification of individuals with chronic heart failure at elevated risk of disease progression.
	Patient Instructions	Fasting is not required
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	**N/A**
	Transport Temperature	Refrigerated
	Volume	1.0 mL
	Stability	*Ambient:* 22 Days *Refrigerated:* 22 Days *Frozen:* 1 Year
	Rejection Criteria	**1. Specimen other than Preferred** 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Hemolysis
Analysis	**Performing Laboratory**	Cleveland HeartLab, Inc – Cleveland, OH
	Methodology	Enzyme-linked Immunoassay (ELISA)
	Turnaround Time	5 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Ranges: N/A Risk Ranges (*ng/mL)*: *Age* | *Low* | *Moderate* | *High* All Ages | <17.9 | 17.9-25.9 | >25.9

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – Immune

Effective i**mmediately,** Cleveland HeartLab, Inc. will incorporate the following **reference range change** for the Immunoglobulin A (IgA) test. The change is **bolded** in the table below.

	Test Name[a]	Immunoglobulin A (IgA)
Ordering	**Order Code**	C1362
	NY-Approval	82784
	CPT Code[b]	Yes
	Tests Included	Immunoglobulin A
	Clinical Significance	Increased IgA is associated with monoclonal IgA myeloma, respiratory and gastrointestinal infections, and malabsorption; decreased IgA is found in selective IgA deficiency and in ataxia telangiectasia.
	Patient Instructions	Fasting is not required
Processing	**Specimen/ Tube Type[a]**	Serum, Serum Separator Tube (SST; with Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated
	Volume	1.0 mL
	Stability	*Ambient:* 3 Days *Refrigerated:* 7 Days *Frozen:* 90 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross lipemia
Analysis	**Performing Laboratory**	Quest Diagnostics – Pittsburgh, PA
	Methodology	Immunoturbidimetric Assay
	Turnaround Time	2-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Age* / *Reference Range (mg/dL)* Cord Blood: 1-3 1-28 Days: 2-40 1-3 Months: 3-40 4-6 Months: 7-47 7-11 Months: 12-53 1 Year: 20-73 2 Years: 20-99 3-5 Years: 22-140 6-8 Years: 31-180 9-11 Years: 33-200 12-16 Years: 36-220 17-60 Years: 47-310 **≥61 Years: 70-320**

[a] Reference the Test Menu on clevelandheartlab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – Immune

On **Tuesday January 28, 2020** Cleveland HeartLab, Inc. will incorporate the following changes for the **Sjogren's Antibodies (SS-A, SS-B)** test. These changes are **bolded** in the table below.

	Test Name[a]	Sjogren's Antibodies (SS-A, SS-B)
Ordering	**Order Code**	C1388
	NY-Approval	86235 (SS-A); 86235 (SS-B)
	CPT Code[b]	Yes
	Tests Included	SS-A and SS-B Antibodies
	Clinical Significance	Sjogren's Antibodies (SS-A and SS-B) are associated with Sjogren's Syndrome. The presence of both antibodies (SS-A and SS-B) strengthen the diagnosis of Sjogren's Syndrome and conveys prognostic information.
	Patient Instructions	Fasting is not required
Processing	**Specimen/ Tube Type[a]**	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	Serum, Red-Top Tube (without Gel Barrier)
	Transport Temperature	Refrigerated
	Volume	1.0 mL
	Stability	*Ambient:* 4 Days *Refrigerated:* 7 Days *Frozen:* 30 Days
	Rejection Criteria	1. Specimen other than Preferred or Alternate 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Gross hemolysis 6. Gross lipemia **7. Gross icterus**
Analysis	**Performing Laboratory**	**Quest Diagnostics – Chantilly, VA**
	Methodology	Immunoassay (IA)
	Turnaround Time	**2-3 Days**
	Reference Ranges, Risk Ranges, and/or Priority Values	Refer to Reference Ranges provided for individual tests

[a] Reference the Test Menu on clevelandheartlab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – General Chemistry

On **Tuesday January 28, 2020** Cleveland HeartLab, Inc. will incorporate the following **reference range changes** for the Urinalysis, Macroscopic and Urinalysis, Microscopic tests.

Please Note:
These reference range changes (**bolded** below) are also incorporated in **Urinalysis Reflex (Order Code 1382) and Urinalysis, Complete (Order Code C916).**[a,b]

	Test Name[a]	Urinalysis, Macroscopic	Urinalysis, Microscopic
Ordering	**Order Code**	1381	1390
	CPT Code[c]	81003	81015
	NY-Approval	Yes	Yes
	Tests Included	See Reference Range for list of analytes included in Urinalysis, Macroscopic	See Reference Range for list of analytes included in Urinalysis, Microscopic
	Clinical Significance	Dipstick urinalysis is important in accessing the chemical constituents in the urine and the relationship to various diseases.	Microscopic examination to detect the presence of abnormal urine cells and formed elements.
Analysis	**Performing Laboratory**	Cleveland HeartLab, Inc – Cleveland, OH	Cleveland HeartLab, Inc – Cleveland, OH
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Analyte* / *Range/Interpretation* Color: Yellow Appearance: Clear pH: 5.0-8.0 Specific Gravity: 1.001-1.035 **Glucose: Negative** **Bilirubin: Negative** Ketones: Negative **Urobilinogen: *Discontinued*** Occult Blood: Negative **Protein: Negative** Nitrite: Negative **Leukocyte Esterase: Negative**	Reference Range: *Analyte* / *Range/Interpretation* WBC: ≤5 cells/hpf RBC: ≤2 cells/hpf **Squamous Epithelial Cells: ≤5 cells/hpf** Bacteria: None seen/hpf Hyaline Casts: None seen/lpf **Please Note:** Other microscopic elements are reported, if found.

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] **Reflex testing is performed at an additional charge.**
[c] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – Lipoprotein Fractionation

On **Tuesday January 28, 2020** Cleveland HeartLab, Inc. will increase the **specimen volume** requirement (**bolded** below) for the following tests.

<table>
<tr><th></th><th>Test Name[a]</th><th>HDL2b</th><th>sd-LDL</th></tr>
<tr><td rowspan="5">Ordering</td><td>Order Code</td><td>83701</td><td>83722</td></tr>
<tr><td>CPT Code[b]</td><td>1342</td><td>1341</td></tr>
<tr><td>NY-Approval</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Tests Included</td><td>HDL2b</td><td>Small Dense Low-Density Lipoprotein (sd-LDL)</td></tr>
<tr><td>Clinical Significance</td><td>The HDL2b test may be used for individuals at risk of diabetes or cardiovascular disease, those with cardiovascular disease or those with low total HDL levels or high triglyceride levels.</td><td>The small dense LDL test can be used to determine cardiovascular risk in individuals with metabolic syndrome or established/progressing coronary artery disease.</td></tr>
<tr><td colspan="2">Patient Instructions</td><td>Fasting is not required</td><td>Fasting may be required for this test.</td></tr>
<tr><td rowspan="6">Processing</td><td>Specimen/Tube Type</td><td>Serum, Serum Separator Tube
(SST; Gel Barrier)</td><td>Serum, Serum Separator Tube
(SST; Gel Barrier)</td></tr>
<tr><td>Alternate Specimen/
Tube Type</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Collection Instructions</td><td>Serum specimen must be stored in refrigerated temperature within one hour of collection.

<u>Note:</u> We encourage specimen to be shipped the same day as drawn in order to maintain sample integrity.</td><td>At least 3.0 mL of blood should be drawn.</td></tr>
<tr><td>Transport Temperature</td><td>Refrigerated</td><td>Refrigerated</td></tr>
<tr><td>Volume</td><td>1.0 mL</td><td>1.0 mL</td></tr>
<tr><td>Stability</td><td>Ambient: Not Acceptable
Refrigerated: 5 Days
Frozen: 7 Days</td><td>Ambient: Not Acceptable
Refrigerated: 5 Days
Frozen: Not Acceptable</td></tr>
<tr><td>Rejection Criteria</td><td>1. Specimen other than Preferred
2. Improper labeling
3. Specimen not stored properly
4. Specimen older than stability limits
5. Gross hemolysis
6. Gross lipemia
7. Gross icterus</td><td>1. Specimen other than Preferred
2. Improper labeling
3. Specimen not stored properly
4. Specimen older than stability limits</td></tr>
<tr><td rowspan="4">Analysis</td><td>Performing Laboratory</td><td>Cleveland HeartLab, Inc – Cleveland, OH</td><td>Cleveland HeartLab, Inc – Cleveland, OH</td></tr>
<tr><td>Methodology</td><td>Microfluidics Electrophoresis</td><td>Enzymatic Assay</td></tr>
<tr><td>Turnaround Time</td><td>5 Days</td><td>3 Days</td></tr>
<tr><td>Reference Ranges,
Risk Ranges,
and/or
Priority Values</td><td><u>Reference Ranges:</u>
N/A

<u>Risk Ranges</u>:
<table><tr><th>Sex</th><th>Low</th><th>Moderate</th><th>High</th></tr><tr><td>Male</td><td><18%</td><td>18-26%</td><td>>26%</td></tr><tr><td>Female</td><td><18%</td><td>18-28%</td><td>>28%</td></tr></table></td><td><u>Reference Ranges:</u>
N/A

<u>Risk Ranges</u>:
<table><tr><th>Sex</th><th>Optimal (mg/dL)</th></tr><tr><td>Male & Female (Adult)</td><td><50.0</td></tr></table></td></tr>
</table>

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

II. Changes to Existing Tests – Vitamins/Supplements

On **Tuesday January 28, 2020** Cleveland HeartLab, Inc. will change **refrigerated stability** for **Folate, Serum**, which is **bolded** in the table below.

	Test Name[a]	Folate, Serum
Ordering	**Order Code**	**C258**
	NY-Approval	Yes
	CPT Code[b]	82746
	Tests Included	Folate, Serum
	Clinical Significance	A folate test can be used in the diagnosis of the cause of anemia or neuropathy, to evaluate nutritional status in some individuals, or to monitor effectiveness of treatment for Vitamin B12 or folate deficiency.
	Patient Instructions	Fasting is preferred, but not required for this test. Specimen should not be taken from patients receiving therapy with high biotin doses (ie >5 mg/day) until at least 8 hours following the last biotin administration.
Processing	**Specimen/Tube Type**	Serum, Serum Separator Tube (SST; Gel Barrier)
	Alternate Specimen/ Tube Type	N/A
	Transport Temperature	Refrigerated
	Volume	**0.5 mL**
	Stability	*Ambient:* **Unacceptable** *Refrigerated:* **6 Days** *Frozen:* 4 Weeks
	Rejection Criteria	1. Specimen other than Preferred 2. Improper labeling 3. Specimen not stored properly 4. Specimen older than stability limits 5. Hemolysis 6. Specimen which are heat-inactivated 7. Specimen stabilized with azide
Analysis	**Performing Laboratory**	Cleveland HeartLab, Inc – Cleveland, OH
	Methodology	Electrochemiluminescence Immunoassay (ECLIA)
	Turnaround Time	1-3 Days
	Reference Ranges, Risk Ranges, and/or Priority Values	Reference Range: *Age* | *Range (ng/mL)* All Ages | 4.8-24.2

[a] Reference the Test Menu on ClevelandHeartLab.com for additional details (processing/shipping requirements, reference ranges, etc).
[b] The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Please note that changes to existing tests will not impact profile prices from previously signed agreements. If you would like to make changes to custom profiles, please contact your Sales Representative.

Cleveland HeartLab is dedicated to providing quality lab results to you and your patients. Please do not hesitate to contact us at 1.866.358.9828, Option 1, if there are any questions or concerns.

Kind Regards,

Deborah H. Sun, PhD, DABCC, FACB
Sr. Laboratory Operations Director

Bill Richendollar, MD
Medical Director