PACIFIC DIAGNOSTIC LABORATORIES
Guiding Health™

January 3, 2019

Announcement

Laboratory Changes
Go-Live: January 8, 2019

Pacific Diagnostic Laboratories' (PDL) next generation chemistry immunoassay analyzers have passed our demanding standards of reliability in both technical and informatics and will be going live on Tuesday, January 8th. As previously communicated, there will be changes with reference ranges and cardiac testing. For your reference, updated communications are attached.

Stewart W. Comer MD.
Stewart W. Comer, MD FCAP
Medical Director
Pacific Diagnostic Laboratories

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Chemistry Reference Range Changes
Effective January 8, 2019

With the advent of new laboratory technology, PDL is pleased to announce the implementation of newer generation chemistry and immunoassay analyzers. Our transition date is targeted for January 8, 2019. The adoption of these new analyzers has resulted in revised normal reference ranges which are listed below comparing the current with the new reference range. Additionally we will be moving to more sensitive cardiac markers, specifically NT pro-BNP and contemporary sensitive cardiac Troponin I. There will be further detailed information communicated on these cardiac analytes.

If you have any questions or concerns regarding these changes, I can be reached at (805) 569-7367.

Stewart W. Comer MD.

Stewart W. Comer, MD
Medical Director
Pacific Diagnostic Laboratories

Revised Reference Ranges for Chemistry instrumentation, effective January 8, 2019

TEST	Units	Current Reference Range	New Reference Range
ALT (Alanine Aminotransferase)	U/L	Female: <45 Male: <50	Female: 13-56 Male: 16-61
Albumin	g/dL	3.7 – 5.0	3.4 – 5.0
Alkaline Phosphatase	U/L	<135	45 – 117
Amylase	U/L	<160	25 - 115
AST (Aspartate Aminotransferase)	U/L	Female: <43 Male: <50	15 - 37
Bilirubin, Direct	mg/dL	<0.3	0.0 – 0.2
Bilirubin, Total	mg/dL	<1.4	0.2 – 1.0
BUN (Blood Urea Nitrogen)	mg/dL	8.0 – 26.0	7.0 – 18.0
CK (Creatinine Kinase)	U/L	Female: <160 Male: <300	Female: 26 - 192 Male: 39 - 308
Creatinine	mg/dL	Female: 0.4 – 1.2 Male: 0.6 – 1.4	Female: 0.55 – 1.02 Male: 0.7 – 1.30
GGT (Gamma Glutamyl Transferase)	U/L	Female: <70 Male: <85	Female: 5.0 - 55 Male: 15 - 85
Iron	ug/dL	Female: 37 - 145 Male: 59 - 158	Female: 50 - 170 Male: 65 - 175

Revised Reference Ranges for Chemistry instrumentation, effective January 8, 2019

TEST	Units	Current Reference Range	New Reference Range
Lipase	U/L	<56	73 – 393
LDH (Lactate Dehydrogenase)	U/L	<265	Female: 84 - 246 Male: 87 - 241
TIBC (Total Iron Binding Capacity)	ug/dL	230 - 440	250 - 450
Uric Acid	mg/dL	Female: 2.9 – 7.1 Male: 3.8 – 8.4	Female: 2.6 – 6.0 Male: 3.5 – 7.2

Revised Reference Ranges for Special Chemistry instrumentation, effective January 8, 2019

TEST	Units	Current Reference Range	New Reference Range
Acetaminophen	ug/mL	10.0 – 25.0	10.0 – 30.0
Ammonia	umol/L	11 - 35	13 – 54
Beta-2-microglobulin	mg/L	0.97 – 1.84	0.61 – 2.30
BNP	pg/mL	<100	No longer available
NT-proBNP	pg/mL		0 - 75 years: <125 >75 years: <450
Cancer Antigen 125	U/mL	<35	1.5 – 35.0
Cancer Antigen 15-3	U/mL	<32.4	1.5 – 35.0
Cancer Antigen 19-9	U/mL	<35	2.0 – 37.0
Carcinoembryonic Antigen	ng/mL	<2.5	<3.0; Smokers <5.0
Complement C3	mg/dL	98 – 201	90 – 180
Complement C4	mg/dL	18 – 56	10 – 40
C-Peptide	ng/mL	0.80 – 3.10	0.81 – 3.85
Estradiol	pg/mL	Female Result Comment: *Follicular phase 19 – 247* *Mid-cycle phase 36 – 571* *Luteal phase 22 – 256* *Post-menopausal <44* Male Reference Range: None	Female Result Comment: *Follicular phase 21.4 – 164.8* *Mid-cycle phase 49.9 – 367.2* *Luteal phase 40.2 – 259.0* *Post-menopausal On Menopausal Hormone Therapy (MHT) <11 – 462.1* *Untreated <11 – 58.3* Male Reference Range: <11 – 52.5
Ferritin	ng/mL	Female: 10 – 291 Male: 22 – 322	Female: 8 – 252 Male: 26 – 388
Folate	ng/mL	>2.8	>4.0
Follicle Stimulating Hormone	mIU/mL	Female Result Comment: *Follicular phase 2.3 – 10.2* *Mid-cycle phase 4.5 – 33.0* *Luteal phase 1.9 – 9.0* *Post-menopausal 23.0 – 117.0*	Female Result Comment: *Follicular phase 2.3 – 12.6* *Mid-cycle phase 5.2 – 17.5* *Luteal phase 1.7 – 9.5* *Post-menopausal On Menopausal Hormone Therapy (MHT) 5.9 – 72.8* *Untreated 12.7 – 132.2*

Revised Reference Ranges for Special Chemistry instrumentation, effective January 8, 2019

TEST	Units	Current Reference Range	New Reference Range
		Male Reference Range: 1.5 – 18.1	Male Reference Range: 0.7 – 10.8
Free Thyroxine	ng/dL	0.8 – 1.7	0.76 – 1.46
Free Triiodothyronine	pg/mL	2.34 – 4.2	2.18 – 3.98
Growth Hormone	ng/mL	Female: <10.0 Male: <1.0	Female: 0.0 – 8.0 Male: 0.0 – 3.0
Homocysteine	umol/L	4.5 – 12.0	2.0 – 13.0
Immunoglobulin A	mg/dL	63 – 498	70 – 400
Immunoglobulin G	mg/dL	746 - 1774	700 – 1600
Immunoglobulin M	mg/dL	63 – 300	40 – 230
Luteinizing Hormone	mIU/mL	Female Result Comment: *Follicular phase 1.9 – 12.0* *Mid-cycle phase 9.0 – 76.0* *Luteal phase 0.5 – 16.0* *Post-menopausal 11.0 – 59.0* Male Reference Range: 1.5 – 9.3	Female Result Comment: *Follicular phase 1.9 – 12.8* *Mid-cycle phase 22.8 – 76.1* *Luteal phase 0.6 – 13.5* *Post-menopausal On Menopausal Hormone Therapy (MHT) 1.1 – 52.4 Untreated 8.6 – 61.8* Male Reference Range: 1.2 – 10.6
Methotrexate	umol/L	<0.05	<0.05
Progesterone	ng/mL	Female Result Comment: *Follicular phase 0.2 – 1.4* *Luteal phase 4.0 – 25.0* *Post-menopausal <0.15 – 0.7* *Pregnant* *First Trimester 11.2 – 90.0* *Second Trimester 25.6 – 89.4* *Third Trimester 48.4 – 422.5* Male Reference Range: 0.3 – 1.0	Female Result Comment: *Follicular phase 0.210 – 1.70* *Mid-cycle phase 2.25 – 24.2* *Luteal phase 8.76 – 21.6* *Post-menopausal <0.200 – 0.901* *Pregnant* *First Trimester 11.4 – 41.0* *Second Trimester 13.8 – 156* *Third Trimester 51.4 - >200* Male Reference Range: <0.200 – 1.97
Prolactin	ng/mL	Female Result Comment: *Non-pregnant 3.3 – 26.7* *Pregnant 10.0 – 210.0* *Post-menopausal 2.4 – 20.0* Male Reference Range: 2.1 – 18.0	Female Result Comment: *Non-pregnant 2.2 – 30.3* *Pregnant 8.1 – 347.6* *Post-menopausal 0.7 – 31.5* Male Reference Range: 2.5 – 17.4
Rheumatoid Factor	IU/mL	<14	<15
Thyroid Stimulating Hormone	uIU/mL	0.35 – 5.50	0.358 – 3.74
Total Beta HCG	mIU/mL	Female Result Comment: *Non-pregnant <10* *hCG levels with Gestational Age* *0.2–1 week 5–50* *1–2 weeks 50–500*	Female Result Comment: *Non-pregnant* 1 – 3 *hCG levels with Gestational Age* *0.2–1 week 5–50* *1–2 weeks 50–500*

Revised Reference Ranges for Special Chemistry instrumentation, effective January 8, 2019

TEST	Units	Current Reference Range	New Reference Range
		2–3 weeks 100–5000 *3–4 weeks 500–10,000* *4–5 weeks 1,000–50,000* *5–6 weeks 10,000–100,000* *6–8 weeks 15,000–200,000* *2–3 months 10,000–100,000*	*2–3 weeks 100–5000* *3–4 weeks 500–10,000* *4–5 weeks 1,000–50,000* *5–6 weeks 10,000–100,000* *6–8 weeks 15,000–200,000* *2–3 months 10,000–100,000* Male Reference Range: ≤1.0
Total Prostate Specific Antigen	ng/mL	Female: <4.0 Male: 0 – 50 <2.50 50 – 60 <3.50 60 – 70 <4.50 70 – <6.50	Female: N/A Male: <4.0
Total T4	ug/dL	4.7 – 13.3	Female: 4.8–13.9 Male: 4.5–12.1
Troponin	ng/mL	<0.06	<0.045
Vitamin B12	pg/mL	>211	193 – 986

January 3, 2019

Announcement

Changes with BNP and CTNI Cardiac Laboratory Tests Effective January 8, 2019

Effective January 8, 2019, Pacific Diagnostic Laboratories (PDL) will be transitioning to more sensitive and robust cardiac test for NT pro-BNP and cardiac Troponin I (cTnI). This is intended to improve the quality and reliability of cardiac laboratory testing to help facilitate the medical decision-making process on behalf of our providers. It is important to recognize that the specific numerical values obtained from NT proBNP and new sensitive cTnI assays are NOT equivalent and cannot be compared or interchanged with the current test method values. Each test is designed to be interpreted within the context of the new reference ranges.

The key aspects of these assays are noted below:

1. B-type natriuretic peptide (BNP) and NT-proBNP are cardiac biomarkers measuring different products of the larger proBNP molecule. Two key benefits to NT-proBNP that helps increase the sensitivity in comparison to BNP is the increased half-life (6x) and preanalytic stability (3x). Recent clinical evidence (Ref 1) suggests that NT-proBNP is a superior marker of heart failure compared to BNP particularly given the age-stratified cutoff values (< 75 years at 125 pg/mL and ≥ 75 years: 450 pg/mL) and greater sensitivity for the detection of chronic heart failure in patients with preserved left ventricular ejection fraction. The Natriuretic Peptide Levels across Stages of Heart Failure for BNP and NT-proBNP values (median, 25th – 75th percentile) in patients classified according to AHA/ACC classification:

	Stage A	Stage B	Stage C	Stage D
BNP (ng/L)	11 (5 – 19)	20 (10-40)	165 (52 – 378)	404 (182-1,102)
NT-proBNP (ng/L)	43 (26-85)	88 (43-224)	1,136 (379-2,824)	4,394 (1467-10,184)

BNP and NT-proBNP for early diagnosis of heart failure. Clin. Chem. 2007; 53:1289-1297

2. Cardiac troponin I (cTnI) testing is designed to biochemically detect myocardial injury and is an important criterion of the international definition of myocardial infarction (MI). The Universal Definition of MI as delineated in the 2018 Consensus Document (Ref 2) is predicated on both MI types and specific laboratory criteria:
    a. Criteria for Acute Myocardial Infarction (types 1, 2 and 3 MI)
        i. Rise and/or fall in cTnI with at least one cTnI value greater than the 99th percentile URL (0.045 ng/mL).
        ii. Symptoms of myocardial ischemia, new ischemic ECG changes, pathologic Q waves, or select radiographic features.
        iii. Criteria for Procedure-related Myocardial Infarction (types 4 and 5 MI)
    b. Criteria for Procedure-related Myocardial Infarction (types 4 and 5 MI)
        i. Occurs less than 48 hours after an index procedure with normal baseline cTnI
        ii. Greater than 5 times 99th percentile (URL) for type 4a (PCI)
        iii. Greater than 10 times 99th percentile (URL) for type 5 (CABG)

    According to the Universal Definition, a diagnosis of MI is not intended to be decided based on one value alone. Regardless of whether the initial cTnI result is normal or increased above the 99th percentile value, the critical component for the diagnosis of an acute MI requires a directional trend in cTnI values. This definition inherently requires at least two cTnI results, which can display either a rising or falling pattern, over the initial 0–12 hours after a patient's presentation (0h) with at least one value above the 99th percentile. This is why serial cTnI orders, and not a single isolated cTnI order, is essential to biochemically define an MI

    NOTE: Transition for CTNI will be patient based. Patients that began serial draws on current method will complete their testing on the current method.

    Ref 1: *International Collaborative NT-proBNP Study*: Eur Heart J (2006) Vol 27: 330-337.
    Ref 2: *Fourth Universal Definition of* MI: *Circulation (2018)* Vol 138(20): e618-651.

If you have any questions or concerns regarding these changes, I can be reached at (805) 569-7367.

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