Policy for Priority Result Reporting

Purpose/Introduction

The Quest Diagnostics Priority Result Reporting Policy describes the reporting of test results assigned a variable level of Priority (P1 or P2) depending on thresholds established and amended by medical consensus and approved by the Chief Medical Officer or designee. The Priority Result Reporting Policy is in addition to the regular reporting procedure for all test results (such as reports delivered by mail or electronically).

The provider who requests the test is responsible for providing 24-hour reliable contact information for the purpose of priority reporting.

We will notify the ordering provider or authorized representative as permitted or required by state and federal law. Thereafter, the provider or authorized representative has the responsibility of interpreting the result in the context of the patient's clinical condition and to take appropriate action, if needed. If the person notified is not qualified to make these decisions, they have a responsibility to communicate the information to a qualified person immediately.

Priority Level Definitions

Priority–1 test results are reported 24 hours/day and 7 days/week and may be "critical" as referenced in the Clinical Laboratory Improvement Amendments of 1988 (CLIA; CFR 493.1291g) and the CAP Laboratory Accreditation Program.

Priority–2 test results are reported during office hours if known, or 9 am to 5 pm, 7 days/week and may require attention prior to the receipt of routine laboratory reports. When we are informed that office is closed for the day by answering service or voice message, we will fax (if available) or mail/deliver the results alerting you of the Priority 2 value(s).

For facilities that are known to us as a nursing home or hospital, we will use reasonable efforts to promptly communicate Priority results 24 hours/day and 7 days/week.

The Priority Value Table thresholds will not be customized (changes, deletions, or additions) without a signed client request and approval by the laboratory medical director or regional medical director.

Sincerely,

Enrique Terrazas, MD, MS

Senior Medical Director Medical Quality

Priority Value Tables by Testing Department

Chemistry / Special Chemistry		Priority 1 *(called 24 hrs, 7 days)*			Priority 2 *(office hours, 7 days)*		
Analyte		**Age**	**Low**	**High**	**Age**	**Low**	**High**
Ammonia	[umol/L]	≤18 y		>200			
Amylase	[U/L]				All		≥300
Bilirubin, total	[mg/dL]	≤2 y		≥15.0			
Calcium, total	[mg/dL]	All	≤6.0	≥13.0			
Calcium, ionized	[mg/dL]	All	≤3.2	>6.9			
CK–MB					All		>positive cutoff value (varies with assay)
CK	[U/L]				≤18 y		≥1000
					>18 y		≥6000
Creatinine	[mg/dL]				All		≥8.00
Galactose, urine	[mg/dL]				≤2 y		>70
Galactose–1–Phosphate	[mg/dL]				≤2 y		>5.0
Glomerular Basement Membrane Ab IgG,	[AI]	All		≥1.0			
Glucose, serum ** Glucose results are flagged **P1–P2** regardless of ordered test (OGTT, random glucose, serum or plasma). When results are called to the client, the report title of the test result should be made known to the client.*	[mg/dL]	All	<40	≥500	All		400–499
Glucose, CSF,	[mg/dL]	All	<30				
Lipase	[U/L]				All		≥180
Magnesium, serum or plasma	[mg/dL]	All	≤1.0	≥6.1			
Phosphate (as phosphorus), serum or plasma	[mg/dL]	All	≤1.0				
Potassium, serum or plasma	[mmol/L]	All	≤2.7	≥6.2			
Sodium, serum or plasma	[mmol/L]	All	≤120	≥160			
Transferrin, Beta-2					All		Positive (Detected)
Troponin (I or T)	[ng/mL]	All		Positive >cutoff value			
Troponin, High Sensitivity (I or T)	[ng/L]	All		Positive >cutoff value			
TSH	[mIU/L]				≤1 y		≥40.00
Uric Acid	[mg/dL]				All		>14.0
Viscosity, serum	[relative to water]	All		≥3.0			

Hematology / Coagulation / Urinalysis		Priority 1 *(called 24 hrs, 7 days)*			Priority 2 *(office hours, 7 days)*		
Analyte		**Age**	**Low**	**High**	**Age**	**Low**	**High**
Hemoglobin	[g/dL]	≤12 y	<7.0	≥22.5	≤12 y	7.0–8.9	
		>12 y	≤6.0	≥22.5	>12 y	6.1–7.0	
WBC	[/uL]				All	<1,000	
Neutrophils, absolute number	[/uL]	All	<400		All		>30,000
Blasts, absolute number	[/uL]	All		≥50,000 *(any patient)*	All		>0 *(new patient)*
Cerebrospinal fluid (CSF)		All	Any abnormal per local Medical Director				
Malaria parasites or other organisms (Babesia, Ehrlichia, Trypanosomes etc.) *[also appears in Microbiology section]*		All	Positive for *P. falciparum* or unspeciated Plasmodium sp. that is possible *P. falciparum*		All	Positive for blood parasites other than *P. falciparum*	
Platelet Count, absolute number	[/uL]	All	<20,000	≥2,000,000			
Partial Thromboplastin Time (aPTT)	[sec.]	All		≥90			
Prothrombin Time - International Normalized Ratio (PT-INR)		All		≥8.0	All		5.0–7.9
ADAMTS13 Activity reflex to Inhibitor (Von Willebrand Factor Protease Cleaving Activity)	[%]	All	≤30				
Coagulation Factor VIII, IX and XI Inhibitor	[Bethesda Unit]				All		>2
Coagulation Factor XIII, Activity	[%]				All	<20	
Coagulation Factors VIII & IX, Activity	[%]	All	<5				
Cryoglobulin	[%]				All		≥ 3
Fibrinogen Clotting Activity, Clauss	[mg/dL]				All	<50	
Heparin	[IU/mL]				All		>2.0
Heparin-Induced Platelet Antibody					All		Positive
Serotonin Release Assay	[%]				All		≥20
Protein C and S Activity %					< 1 month	<10%	

Priority Value Tables by Testing Department

Infectious Agents	Priority 1 *(called 24 hrs, 7 days)*		Priority 2 *(office hours, 7 days)*	
Analyte	**Age**	**Result**	**Age**	**Result**
Aspergillus galactomannan antigen, serum, CSF or bronchoalveolar lavage	All	Detected CSF	All	Detected
Bacillus anthracis, culture, antigen or nucleic acid detection	All	Positive		
Bordetella pertussis, culture, antigen or nucleic acid detection			All	Positive
Bordetella parapertussis, culture, antigen or nucleic acid detection			All	Positive
Brucella sp., culture, antigen or nucleic acid detection	All	Positive		
California Encephalitis virus IgM (Serum, CSF)			All	Detected
Chlamydia trachomatis, culture, nucleic acid or antigen test			<13 y	Positive
Clostridium difficile toxin A/B and GDH Antigen are both positive, or positive PCR, cytotoxicity assay or toxigenic culture (Note: non-toxigenic strains will not be called)			All	Detected
Corynebacterium diphtheriae, nasopharynx culture	All	Positive		
Cryptococcus antigen, serum or CSF	All	Detected		
Culture (Any type): blood, CSF, any tissue or sterile body fluid (excluding urine and *H. pylori* from tissue biopsy)	All	PRELIM: positive any organism	All	FINAL: positive any organism
Cytomegalovirus,nucleic acid detection and culture: All sterile body fluid including blood sources (serum, plasma, whole blood) [excluding quantitative CMV from blood sources, and genotyping]	All	Positive	<1 y	Positive in urine or saliva
Culture, Herpes Simplex Virus	<4 mos	Positive		
Eastern Equine Encephalitis virus IgM (Serum, CSF)			All	Detected
E coli O157, culture, stool			All	Positive
Enterobacteriaceae isolates (other than Proteus, Providencia and Morganella)			All	Resistant to any Carbapenem
Francisella tularensis, culture, antigen or nucleic acid detection	All	Positive		
Gram or other stain of direct specimen or antigen detection (blood, CSF, sterile tissue or body fluids)	All	Positive or Detected		
Nucleic acid detection: All sterile body fluid including blood sources (serum, plasma, whole blood) [excluding quantitative HIV, HCV, HBV, BKV, EBV from blood sources, and genotyping]	All	Positive: HSV, VZV,Leptospira, Rickettsial species Kingella	All	Positive for other microorganisms (Excluding borrelia species from blood source and HIV qualitative NAAT: no call)
Histoplasma, *Blastomyces*, *Coccidiodes*, *Paracoccidiodes*, *Cryptococcus* species, or *Candida auris* isolated and/or detected by microscopy, antigen or nucleic acid detection	All	Positive on blood or CSF	All	Positive
Legionella sp., culture, nucleic acid, or antigen test			All	Positive

Priority Value Tables by Testing Department

Infectious Agents	Priority 1 *(called 24 hrs, 7 days)*		Priority 2 *(office hours, 7 days)*	
Analyte	**Age**	**Result**	**Age**	**Result**
Malaria parasites or other blood parasites (e.g., *Babesia*, *Trypanosomes,* etc.) Antigen or nucleic acid detection, culture, or microscopy	All	Positive for *P. falciparum* or unspeciated Plasmodium sp. that is possible *P. falciparum*	All	Positive for blood parasites other than *P. falciparum*
MRSA culture			All	Positive (patients in extended care or hospital setting)
MRSA nucleic acid detection			All	Detected (patients in extended care or hospital settings)
Mucormycosis/Zygomycosis (lung tissue or sinonasal area)	All	Positive		
Mycobacteria stain or direct specimen nucleic acid test for *M tuberculosis*, initial detection			All	Positive
Mycobacteria culture, all sp., initial detection and final identification			All	Positive
Mycobacteria tuberculosis, susceptibilities, resistant to 2 or more drugs			All	Resistant ≥2
Neisseria gonorrhoeae, culture or nucleic acid detection			<13y	Positive
Nocardia species			All	Positive
Norovirus – Antigen or nucleic acid detection			All	Positive
Pneumocystis jiroveci (carinii), stain, antigen or nucleic acid detection			All	Positive
Respiratory syncytial virus (RSV), culture, antigen or nucleic acid detection			≤3 y	Positive
Rotavirus, antigen test			All	Positive
Shiga Toxin, EIA or nucleic acid detection			All	Detected
Stool Culture, *Shigella* sp., *Listeria* sp., *Salmonella* sp., *Campylobacter* sp., *Vibrio* sp., and/or *Yersinia enterocolitica*			All	Positive
Streptococcus, Group B, culture or nucleic acid detection			<1 y	Positive
Ureaplasma urealyticum, culture, respiratory			<1 y	Positive
Vancomycin Intermediate or Resistant *Staphylococcus aureus* (VISA or VRSA)			All	Vancomycin I or R
Vancomycin Resistant Enterococcus (VRE) culture or nucleic acid detection			All	Detected
West Nile virus IgM, CSF	All	Positive		
Yersinia pestis, culture, antigen or nucleic acid detection	All	Positive		

TDM / Toxicology		Priority 1 *(called 24 hrs, 7 days)*			Priority 2 *(office hours, 7 days)*		
Analyte		**Age**	**Low**	**High**	**Age**	**Low**	**High**
Acetaminophen	[mg/L]	All		≥50			
Acetone	[mg/dL]	All		≥50			
Amitriptyline + Nortriptyline, total	[mcg/L]	All		≥1000	All		600–999
Amobarbital	[mg/L]	All		≥20.0			
Arsenic, blood	[mcg/L]				All		>60
Butalbital	[mg/L]	All		>10.0			
Cadmium, 24hr urine	[mcg/L]	All		>10.0			
Cadmium, blood	[mcg/L]	All		≥30.0	All		10.0–29.9
Caffeine	[mg/L]	All		≥50.0	<1 y		40.0–49.9
Carbamazepine, total	[mg/L]	All		≥20.0			
Carboxyhemoglobin	[% of total Hgb]	All		≥20			
Chlorpromazine	[ng/mL]	All		≥750			
Chlorpromazine	[ng/mL]	All		≥750			
Clomipramine and Metabolite, total	[ng/mL]	All		≥600			
Clozapine	[ng/mL]	All		≥900			
Cobalt, blood	[mcg/L]	All		≥400			
Cobalt, urine	[mcg/L]				All		≥250
Cyanide	[mg/L]	All		≥1.0	All		0.5–0.9
Cyclosporine, trough	[mcg/L]	All		≥600	All		400–599
Desethylamiodarone	[mcg/mL]	All		>2.5			
Desipramine	[mcg/L]	All		≥600			
Diazepam and Nordiazepam, total	[mg/L]	All		≥3.0			
Digoxin	[mcg/L]	All		≥3.0			
Disopyramide	[mg/L]	All		≥7.0			
Doxepin + Nordoxepin, total	[mcg/L]	All		≥600			
Ethanol, serum and blood	[mg/dL]	All		≥250			
Ethosuximide	[mg/L]	All		≥150			
Ethylene glycol	[mg/L]	All		≥100			
Flecainide	[mg/L]	All		≥1.0			
Fluphenazine	[mcg/L]	All		≥50			
Haloperidol, serum	[ng/mL]				All		>20
Ibuprofen	[mg/L]	All		≥100			
Imipramine or Desipramine, total	[mcg/L]	All		≥600			
Isopropanol	[mg/dL]	All		≥50			
Lead, 24hr urine	[mcg/L]				All		≥120
Lead, blood	[mcg/dL]	<18 y		≥45	<6 y		20–44
Levetiracetam, peak	[mg/L]				All		>70
Levetiracetam, trough	[mg/L]				All		>37
Lidocaine	[mg/L]	All		≥6.0			
Lithium	[mmol/L]	All		≥2.0			
Meconium Drug Testing (confirmation)		All		Positive			
Mephobarbital	[mg/L]	All		≥60.0			
Mercury, urine, 24 hr	[mcg/L]	All		≥150			
Mercury, urine, random	[mcg/g creatinine]	All		≥150			

TDM / Toxicology		Priority 1 *(called 24 hrs, 7 days)*			Priority 2 *(office hours, 7 days)*		
Analyte		**Age**	**Low**	**High**	**Age**	**Low**	**High**
Methanol	[mg/dL]	All		≥5			
Methemoglobin	[% of total Hgb]	All		≥35.0			
Methotrexate at 24 h	[µmol/L]	All		≥5.00			
Methsuximide, as Normethsuximide	[mg/L]	All		>40.0			
Mexiletine	[mg/L]	All		≥5.0	All		2.0–4.9
Mycophenolic Acid	[mcg/mL]	All	<0.5		All	0.5–1.0	>3.5
Mycophenolic Acid Glucuronide	[mcg/mL]				All	<35.0	
Nortriptyline	[mcg/L]	All		≥500			
Phenobarbital	[mg/L]	All		≥60.0			
Phenytoin	[mg/L]	All		≥40.0			
Phenytoin, free	[mg/L]	All		>3.0			
Plazomicin	[mcg/mL]	All		≥ 3.0			
Primidone	[mg/L]	All		>15.0			
Procainamide	[mg/L]	All		≥14.0			
Procainamide + NAPA, total	[mg/L]	All		>30.0			
Propafenone	[mg/L]	All		>2.0			
Protriptyline	[mcg/L]	All		>500			
Quinidine	[mg/L]	All		≥10.0			
Salicylates	[mg/L]	All		≥400			
Sirolimus (Rapamycin)	[mcg/L]				All		≥35.0
Tacrolimus (FK 506)	[mcg/L]				All	≤4.9	>20.0
Thallium, blood	[mcg/L]	All		≥80			
Thallium, urine, 24 hr	[mcg/L]	All		≥200			
Theophylline	[mg/L]	<6 m		>10.0			
Theophylline	[mg/L]	≥ 6 m		≥40.0			
Valproic Acid	[mg/L]	All		≥150.0			
Vancomycin, peak	[mg/L]	All		≥80.0	All		>40.0
Vancomycin, random	[mg/L]	All		≥80.0	All		>40.0
Vancomycin, trough	[mg/L]	All		≥80.0	All		>20.0

Genomic Services Testing	Priority 2 *(office hours, 7 days)*
Analyte	**Result**
Acylcarnitine, plasma	Result is consistent with a known or suspected inborn error of metabolism
Acylglycines, Quantitative Panel, Urine	Result is consistent with a known or suspected inborn error of metabolism
Alpha-1 Antitrypsin (AAT) Mutation Analysis	Homozygous positive and positive for z and s
Alpha-Globin Common Mutation Analysis	Positive for 3 or 4 alpha globin genes
Alpha-Globin Gene Deletion or Duplication	Deletion of 3 or 4 alpha globin genes
Amino acid, Limited	Result is consistent with a known or suspected inborn error of metabolism
Amino acid, plasma	Result is consistent with a known or suspected inborn error of metabolism
Amino acid, urine	Result is consistent with a known or suspected inborn error of metabolism
Amniotic fluid open neural tube defect screen	MOM value ≥ 2.0 MOM
Ashkenazi Jewish Panel (4, 11, or 18 test)	Homozygous, or Compound Heterozygous, or Not Interpretable
Beta Globin Gene Dosage Analysis	Homozygous, or Compound Heterozygous
Beta-Globin Complete	Homozygous, or Compound Heterozygous
Biotinidase	Values ≤5.5 nmol/mL/min
Bloom Syndrome DNA Mutation Analysis	Homozygous, or Compound Heterozygous, or Not Interpretable
CAH (21-Hydroxylase Deficiency) Common Mutations	Homozygous, or Compound Heterozygous
Canavan Disease Mutation Analysis	Not Interpretable
Carnitine	Result is consistent with a known or suspected inborn error of metabolism
Carnitine and acylcarnitine	Result is consistent with a known or suspected inborn error of metabolism
Cystic Fibrosis Gene Deletion or Duplication	Homozygous, or Compound Heterozygous
Cystic Fibrosis Screen	Homozygous, or Compound Heterozygous, Clinically Affected, or Not Interpretable
Cystine	Above 150 mmol/mol creatinine
Cystine 24 hr	Above 1000 umol/24 hrs
Dihydrolipoamide Dehydrogenase Deficiency	Homozygous, or Compound Heterozygous, or Not Interpretable
Dihydropyrimidine Dehydrogenase (DPD) Gene Mutation Analysis	Heterozygous and homozygous positive
Factor V Leiden	Homozygous
Factor XI Mutation Analysis (Ashkenazi Jewish)	Homozygous, or Compound Heterozygous
Familial Dysautonomia Mutation Analysis	Not Interpretable
Familial Hypercholesterolemia	Pathogenic or Likely Pathogenic
Familial Hyperinsulinism	Homozygous, or Compound Heterozygous, or Not Interpretable
Familial Mediterranean Fever Mutation Analysis	Homozygous, or Compound Heterozygous
Fanconi's Anemia DNA Mutation Analysis	Homozygous, or Compound Heterozygous, or Not Interpretable
Galactosemia Mutation Analysis	Homozygous, or Compound Heterozygous
Gaucher Disease, DNA Mutation Analysis	Homozygous, or Compound Heterozygous, or Not Interpretable
Glycogen Storage Disease Type Ia Mutation Analysis	Homozygous, or Compound Heterozygous, or Not Interpretable
Hemophilia A (FACTOR VIII) Inversions	Affected male, Affected female
Joubert Syndrome 2	Not Interpretable
Long Chain Acyl-CoA Dehydrogenase (LCHAD) Mutation Analysis	Homozygous, or Compound Heterozygous

Genomic Services Testing	Priority 2 *(office hours, 7 days)*
Analyte	**Result**
Maple Syrup Disease (MSUD) Mutation Analysis (Ashkenazi)	Homozygous, or Compound Heterozygous, or Not Interpretable
Maternal Serum Biochemical Screening	MSS Screen positive for ONTD, Down syndrome; &/or trisomy 18, or High risk for Down syndrome &/or trisomy 18
Medium Chain Acyl-CoA Dehydrogenase (MCAD) Mutation Analysis	Homozygous, or Compound Heterozygous
Mucolipidosis Type IV Mutation Analysis	Not Interpretable
Nemalin Myopathy	Homozygous, or Compound Heterozygous, or Not Interpretable
Niemann-Pick Disease Mutation Analysis	Not Interpretable
Organic acid, comprehensive	Result is consistent with a known or suspected inborn error of metabolism
Organic acid, limited	Result is consistent with a known or suspected inborn error of metabolism
Phenylketonuria (PKU) Mutation Analysis	Homozygous, or Compound Heterozygous
Porphobilinogen	0-18 yr-old: above 3.6 mg/g creat More than 18 yr old: above 2.2 mg/g creat
Porphobilinogen, urine 24 hr	Above 3.4 mg/24 hr
Porphyrins, Fractionated, Plasma	Uroporphyrin: Above 20 mcg/L Protoporphyrin: Above 40 mcg/L
Porphyrins, Fractionated, Quantitative, 24-Hour urine	Uroporphyrin I: Above 200 mcg/g creat Uroporphyrin III: Above 60 mcg/g creat Coproporphyrin III: Above 1000 mcg/g creat
Porphyrins, Total, Plasma	Above 50 mcg/L
Porphyrins, Urine	Uroporphyrin I: Above 200 mcg/g creat Uroporphyrin III: Above 60 mcg/g creat Coproporphyrin III: Above 600 mcg/g creat
Prothrombin (Factor II) 20210G>A Mutation Analysis	Homozygous positive
Serum Methylmalonic Acid	≥2,000nmol/L
SMA Carrier Screen	SMN1 copies = 0
SMA Diagnostic Test	SMN1 copies = 0
Tay-Sachs Disease Mutation Analysis	Not Interpretable
TPMT Genotype	Intermediate metabolizer, poor metabolizer
Usher Syndrome Type IF	Not Interpretable
Usher Syndrome Type III	Not Interpretable
Very Long Chain Fatty Acids	Result is consistent with a known or suspected inborn error of metabolism
Walker Warburg Syndrome	Not Interpretable

Priority Value Tables by Testing Department

Pathology / Hematopathology	**Priority 1** *(called 24 hrs, 7 days)*	**Priority 2** *(office hours, 7 days)*
Ordered Test	**Interpretation**	**Interpretation**
Gyn Cytology (Pap)		• Herpes changes, if pregnancy indicated in LIS • Adenocarcinoma in situ • Suspicious for malignancy • Positive for malignancy**
Non–Gyn Cytology		• Suspicious for malignancy • Positive for malignancy**
Hematopathology (including Flow Cytometry, FISH, and Molecular)	This section should be customized by the local Laboratory Medical Director to reflect the type of testing done in their facility and the client expectations in their area. It is at the discretion of the pathologist to determine the need to call a clinician 24/7 or during office hours, since the decision may differ when the diagnosis is made via comprehensive testing including tissue and flow and molecular or genetic tests, or if only a subset of these tests are ordered. • Initial diagnosis of acute leukemia should minimally be considered a P2. • Initial diagnosis of acute promyelocytic leukemia, or Clinical Impression APL (with either positive or negative findings) should be considered a P1.	
Tissue Biopsy	• Frozen section results • Presence of adipose tissue in an endometrial biopsy	• POC without identifiable placental villi or fetal parts • Suspicious for malignancy** • Positive for malignancy** • Significant unexpected surgical pathology findings as determined by pathologist

** *Excluding squamous/basal cell skin carcinomas and/or re-excision of known recently diagnosed malignancy but includes cases in which biopsy is a follow-up to cytology report. It is not intended that pre-malignant conditions such as CIN3, high grade PIN, complex endometrial hyperplasia, etc. be considered "Suspicious for Malignancy" unless the pathologist has made an additional comment to that effect.*
It is at the discretion of the pathologist to determine if the findings need to be brought to the clinician's attention after office hours.