

## 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

| Chemistry /<br>Special Chemistry  | Priority 1 <i>(called 24 hrs, 7 days)</i> |      |                        | Priority 2 <i>(office hours, 7 days)</i> |     |  |
|---|---|------|------------------------|--|-----|--|
| 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 [mg/dL]<br><i>* 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.</i> | 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 <i>(called 24 hrs, 7 days)</i> |   |                                 | Priority 2 <i>(office hours, 7 days)</i> |  |                            |
|---|---|---|---------------------------------|--|--|----------------------------|
| 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   | ≥100,000                   |
| Neutrophils, absolute number [uL]   | All                                       | <400  |                                 | All                                      |  | >30,000                    |
| Blasts, absolute number [uL]  | All                                       |   | ≥50,000<br><i>(any patient)</i> | All                                      |  | >0<br><i>(new patient)</i> |
| Cerebrospinal fluid (CSF)   | All                                       | Any abnormal per local Medical Director   |                                 |  |  |                            |
| Malaria parasites or other organisms (Babesia, Ehrlichia, Trypanosomes etc.)<br><i>[also appears in Microbiology section]</i> | All                                       | Positive for <i>P. falciparum</i> or unspiciated Plasmodium sp. that is possible <i>P. falciparum</i> |                                 | All                                      | Positive for blood parasites other than <i>P. falciparum</i> |                            |
| 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%   |                            |

| Infectious Agents  | Priority 1 <i>(called 24 hrs, 7 days)</i> |  | Priority 2 <i>(office hours, 7 days)</i> |  |
|--|---|--|--|--|
| Analyte  | Age                                       | Result   | Age                                      | Result   |
| <i>Aspergillus galactomannan</i> antigen, serum, CSF or bronchoalveolar lavage   | All                                       | Detected CSF   | All                                      | Detected   |
| <i>Bacillus anthracis</i> , culture, antigen or nucleic acid detection   | All                                       | Positive   |  |  |
| <i>Bordetella pertussis</i> , culture, antigen or nucleic acid detection   |   |  | All                                      | Positive   |
| <i>Bordetella parapertussis</i> , culture, antigen or nucleic acid detection   |   |  | All                                      | Positive   |
| <i>Brucella</i> sp., culture, antigen or nucleic acid detection  | All                                       | Positive   |  |  |
| California Encephalitis virus IgM (Serum, CSF)   |   |  | All                                      | Detected   |
| <i>Campylobacter</i> sp. culture, antigen or nucleic acid detection  |   |  | All                                      | Detected or Isolated   |
| <i>Chlamydia trachomatis</i> , culture, nucleic acid or antigen test   |   |  | <13 y                                    | Positive   |
| <i>Clostridium difficile</i> 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   |
| <i>Corynebacterium diphtheriae</i> , nasopharynx culture   | All                                       | Positive   |  |  |
| <i>Cryptococcus</i> antigen, serum or CSF  | All                                       | Detected   |  |  |
| Culture (Any type): blood, CSF, any tissue or sterile body fluid (excluding urine and <i>H. pylori</i> from tissue biopsy)   | All                                       | PRELIM:<br>positive any organism                                   | All                                      | FINAL:<br>positive any organism  |
| <i>Cytomegalovirus</i> , nucleic acid detection and culture:<br>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   |
| <i>E coli</i> O157, culture, stool   |   |  | All                                      | Positive   |
| <i>Enterobacteriaceae</i> isolates (other than <i>Proteus</i> , <i>Providencia</i> and <i>Morganella</i> )   |   |  | All                                      | Resistant to any Carbapenem  |
| <i>Francisella tularensis</i> , 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:<br>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:<br>HSV, VZV, Leptospira, Rickettsial species<br>Kingella | All                                      | Positive for other microorganisms (Excluding borrelia species from blood source and HIV qualitative NAAT: no call) |
| <i>Histoplasma</i> , <i>Blastomyces</i> , <i>Coccidioides</i> , <i>Paracoccidioides</i> , <i>Cryptococcus</i> species, or <i>Candida auris</i> isolated and/or detected by microscopy, antigen or nucleic acid detection | All                                       | Positive on blood or CSF   | All                                      | Positive   |

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

| TDM / Toxicology                     |                    | Priority 1 <i>(called 24 hrs, 7 days)</i> |     |          | Priority 2 <i>(office hours, 7 days)</i> |     |           |
|--------------------------------------|--------------------|---|-----|----------|--|-----|-----------|
| 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 <i>(called 24 hrs, 7 days)</i> |      |        | Priority 2 <i>(office hours, 7 days)</i> |         |         |
|---|---|------|--------|--|---------|---------|
| 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 $\geq 2.0$ 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 $\leq 5.5$ 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   |                        |
| Mucopolipidosis 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<br>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  |                        |

| Pathology / Hematopathology   | Priority 1<br><i>(called 24 hrs, 7 days)</i>  | Priority 2 <i>(office hours, 7 days)</i>   |
|---|---|--|
| Ordered Test  | Interpretation  | Interpretation   |
| Gyn Cytology (Pap)  |   | <ul style="list-style-type: none"> <li>• Herpes changes, if pregnancy indicated on requisition</li> <li>• Adenocarcinoma in situ</li> <li>• Suspicious for malignancy</li> <li>• Positive for malignancy**</li> </ul>  |
| Non-Gyn Cytology  |   | <ul style="list-style-type: none"> <li>• Suspicious for malignancy</li> <li>• Positive for malignancy**</li> </ul>   |
| Hematopathology (including Flow Cytometry, FISH, and Molecular)   | <p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• Initial diagnosis of acute leukemia should minimally be considered a P2.</li> <li>• Initial diagnosis of acute promyelocytic leukemia, or Clinical Impression APL (with either positive or negative findings) should be considered a P1.</li> </ul> |  |
| Tissue Biopsy   | <ul style="list-style-type: none"> <li>• Frozen section results</li> <li>• Presence of adipose tissue in an endometrial biopsy</li> </ul>   | <ul style="list-style-type: none"> <li>• POC without identifiable placental villi or fetal parts</li> <li>• Suspicious for malignancy**</li> <li>• Positive for malignancy**</li> <li>• Significant unexpected surgical pathology findings as determined by pathologist</li> </ul> |
| <p><b>** 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.</b></p> <p><i>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.</i></p> |   |  |