ANALYTE	**REFERENCE RANGE** (LOW RISK)	**ALERT RANGES** (MODERATE OR ELEVATED RISK)	**RESULTS QUALIFIERS** **(Newborn screening results are not diagnostic. Screen positive results must be confirmed by diagnostic testing and clinical evaluation.)**
Carnitine (C0)	C0 > 6.0 µmol/L	C0 ≤ 6.0 µmol/L – Elevated	Acylcarnitine results are included in the tests Fatty Acid Profile and Organic Acid Profile. A ***reference range*** of "Profile" for these tests indicates that results are within reference range. Acylcarnitine analyte results that are outside reference range will be displayed on reports. Results of the Fatty Acid Profile and Organic Acid Profile tests will be reported as **Inconclusive if age at time of specimen collection is less than 24 hours**.
Propionylcarnitine (C3)	C3 < 5.0 µmol/L and C3/C2 < 0.3	5.0 ≤ C3 < 8 µmol/L and C3/C2 ≥ 0.3 – Moderate 8 ≤ C3 < 10 µmol/L and C3/C2 < 0.3 – Moderate 8 ≤ C3 < 10 µmol/L and C3/C2 ≥ 0.3 – Elevated ≥ 10 µmol/L – Elevated	
Butyrylcarnitine (C4)	C4 < 1.4 µmol/L	C4 ≥ 1.4 µmol/L – Elevated	
Isovalerylcarnitine (C5)	C5 < 1.0 µmol/L	C5 ≥ 1.0 µmol/L – Elevated	
Glutarylcarnitine (C5DC)	C5DC < 0.8 µmol/L	C5DC ≥ 0.8 µmol/L – Elevated	
3-OH Isovalerylcarnitine (C5OH)	C5OH < 0.8 µmol/L	C5OH ≥ 0.8 µmol/L – Elevated	
Octanoylcarnitine (C8)	C8 < 0.6 µmol/L	C8 ≥ 0.6 µmol/L – Elevated	
Tetradecenoylcarnitine (C14:1)	C14:1 < 0.8 µmol/L	C14:1 ≥ 0.8 µmol/L – Elevated	
Palmitoylcarnitine (C16)	C16 < 8.5 µmol/L	C16 ≥ 8.5 µmol/L – Elevated	
3-OH-Palmitoylcarnitine (C16OH)	C16OH < 0.09 µmol/L	C16OH ≥ 0.09 µmol/L – Elevated	
Arginine (ARG)	ARG < 110 µmol/L	ARG ≥ 110 µmol/L – Elevated	Results for succinyl acetone, citrulline, and amino acids are included in the test, Amino Acid Profile. A ***reference range*** of "Profile" for these tests indicates that results are within reference range. Results of newborn screening for Amino Acid Profile analytes will be reported as **Inconclusive** if multiple (more than one) amino acid result value is outside reference range (XAA) or **if age at time of specimen collection is less than 24 hours**.
Citrulline (CIT)	CIT < 75 µmol/L	CIT ≥ 75 µmol/L – Elevated	
Leucine (LEU)	LEU < 400 µmol/L and	LEU ≥ 400 µmol/L – Elevated	
Methionine (MET)	MET < 100 µmol/L	MET ≥ 100 µmol/L – Elevated	
Phenylalnine (PHE)	PHE < 160 µmol/L	PHE ≥ 160 µmol/L – Elevated	
Tyrosine (TYR)	TYR < 400 µmol/L	TYR ≥ 400 µmol/L – Elevated	
Succinylacetone (SuAc)	SuAc < 1.7 µmol/L	SuAc ≥ 1.7 µmol/L – Elevated	
17-OH-progesterone (17-OH-P)	17-OH-P < 120 ng/mL S and > 0.5 ng/mL S	17-OH-P ≥ 120 ng/mL S for infant weighing **1500 g or less** – Elevated	17-OH-progesterone results will be reported as **Inconclusive if weight and/or age at time of collection are** not provided. 17-OH-P results are reported as ng/mL S, where S denotes serum, and are calculated (not actually measured in serum) based on conversion factors that assume 55% hematocrit (actual hemotocrit is not measured).
	17-OH-P < 90 ng/mL S and > 0.5 ng/mL S	17-OH-P ≥ 90 ng/mL S for infant weighing **1501-2000 g** – Elevated	
	17-OH-P < 75 ng/mL S and > 0.5 ng/mL S	17-OH-P ≥ 75 ng/mL S for infant weighing **2001-2500 g** – Elevated	
	17-OH-P < 35 ng/mL S and > 0.5 ng/mL S	17-OH-P ≥ 35 ng/mL S for infant weighing **2501 g or more** – Elevated	
		17-OH-P ≥ 240 ng/mL S for infant of **any weight** - Elevated	
TSH	**For specimens collected at ≥ 24 and ≤ 48 hours of age:** 0.5 µU/mL S ≤ TSH < 34 µU/mL S **OR** TSH < 34 µU/mL S and T4 > 8.0 µg/dL	TSH < 34 µU/mL and T4 ≤ 8 µg/dL at **≥ 24 to ≤ 48 hrs** – Moderate 34 ≤ TSH < 50 µU/mL and T4 > 8 µg/dL at **≥ 24 to ≤ 48 hrs** – Moderate 34 ≤ TSH < 50 µU/mL and T4 ≤ 8 µg/dL at **≥ 24 to ≤ 48 hrs** – Elevated	TSH results will be reported as **Inconclusive if age at collection is not provided or if specimen is collected at < 24 hours of age**. TSH results are reported as uIU/mL S, where S denotes serum, and are calculated (not actually measured in serum) based on conversion factors that assume 55% hematocrit (actual hemotocrit is not measured).
	For specimens collected at > 48 hours of age: 0.5 µU/mL S ≤ TSH < 28 uU/mL S **OR** TSH < 28 µU/mL S and T4 > 8.0 µg/dL	TSH < 28 µU/mL S and T4 ≤ 8 µg/dL at **> 48 hrs to ≤ 168 hrs** – Moderate 28 ≤ TSH < 50 µU/mL S and T4 >8 µg/dL at **> 48 hrs to ≤ 168 hrs** – Moderate 28 ≤ TSH < 50 µU/mL S and T4 ≤ 8 µg/dL at **> 48 hrs to ≤ 168 hrs** – Elevated TSH < 0.5 µU/mL S and T4 ≤ 8 µg/dL – Moderate TSH ≥ 50 µU/mL S – Elevated	
	For specimens collected at > 168 hours of age: 0.5 µU/mL S < TSH < 10 uU/mL S OR TSH < 10 µU/mL S and T4 > 8.0 µg/dL	TSH < 10 µU/mL and T4 ≤ 8 µg/dL at **> 168 hrs** – Moderate 10 ≤ TSH < 50 µU/mL and T4 > 8 µg/dL at **> 168 hrs** – Moderate 10 ≤ TSH < 50 µU/mL and T4 ≤ 8 µg/dL at **> 168 hrs** – Elevated TSH ≥ 50 µU/mL – Elevated	

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Biotinidase	Biotinidase > 17 MRU	Biotinidase ≤ 17 MRU – Elevated	Biotinidase will be reported as **Inconclusive if specimen is collected following a transfusion**.
IRT (Cystic Fibrosis)	IRT ≤ 96%ile of daily results **OR** IRT ≤ 160 ng/mL and no mutations on CFTR test panel detected	2 or more CFTR mutations – Elevated 1 CFTR mutation and IRT > 160 ng/mL – Elevated 1 CFTR mutation and IRT ≤ 160 ng/mL – Moderate 0 CFTR mutations and IRT > 160 ng/mL – Moderate	Risk of cystic fibrosis (IRT only or IRT and CFTR results) will be reported as **Inconclusive if specimen is collected following a transfusion** and if results of CFTR mutational analysis are not reproducible or not obtained due to DNA amplification failure. The IRT 96%ile is typically in the range of 56-65 ng/mL.
GALT	GALT > 2.0 U/gHb	GALT ≤ 2.0 U/gHb	GALT results will be reported as **Inconclusive if specimen is collected following a transfusion**.
Hemoglobin	FA	Any result other than FA, with the exception of AF on known transfusion cases FA + any variant – Hemoglobin Trait FS, FC, FSC, or any result lacking Hgb A – Hemoglobin Disease	Hemoglobin results will be reported as **Inconclusive if specimen is collected following a transfusion**.
TRECs (SCID)	TREC CT < 37.700	TREC CT > 39.9 (Absent) and NICU=No, Tx=No, BW>2500g – Elevated 37.7 ≤ TREC CT ≤ 39.9 (Decreased) and NICU=No, Tx=No, BW>2500g – Moderate TREC CT ≥ 37.7 (Decreased) and NICU=Yes, Tx=Yes, and/or BW≤2500g – Moderate	TRECs amplification within reference range is an indicator of normal T cell production; the ***reference range*** for the TREC test is "Normal T cell production". A TREC result of "Decreased" corresponds to decreased TREC DNA amplification and indicates low T-cell production (outside reference range). A TREC result of "Absent" corresponds to no TREC DNA amplification and indicates no T cell production (outside reference range). Risk Level is Inconclusive in the event of DNA amplification failure for both TREC and other unreported reference sequence.
GALC	> 0.65 µmol/L/hr	≤ 0.65 µmol/L/hr – Elevated	The Lysosomal Storage Disorder test includes results of newborn screening for Krabbe (GALC analyte), MPS1 (IDUA analyte) and Pompe (GAA analyte). A reference range of "Profile" for this test indicates that all results are within reference range. Analyte results that are outside reference range will be displayed on reports. Results for GALC will not be displayed if newborn screening for Krabbe has been refused and this is indicated by "Not Tested" on the report. If results for more than one analyte included in the Lysosomal Storage Disorder test is outside reference range, results for IDUA and GAA will be reported as Inconclusive and results for GALC will be reported as Elevated Risk.
IDUA	> 0.65 µmol/L/hr	≤ 0.65 µmol/L/hr – Elevated	
GAA	> 1.10 µmol/L/hr	≤ 1.10 µmol/L/hr – Elevated	

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