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CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Newborn Screening: incorporating a new condition, adding clarity to rules, making updates to practice guidelines

EFFECTIVE DATE: 11/01/2025

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RULES:
333-024-1010, 333-024-1030, 333-024-1070, 333-024-1090

AMEND: 333-024-1010

NOTICE FILED DATE: 09/12/2025

RULE SUMMARY: Amend OAR 333-024-1010

- Adds clarity to the definitions of “high-tier testing” and “kit” and “specimen”

CHANGES TO RULE:

333-024-1010
Newborn Screening: Definitions
As used in OAR 333-024-1000 to 333-024-1110:¶
(1) "Abnormal result" means a laboratory examination result that meets the screening criteria for a newborn screening panel condition requiring additional screening or diagnostic testing and medical follow-up.¶
(2) "Clinical Laboratory Improvement Amendments (CLIA)" means the rules that apply to clinical laboratories in OAR 333-024-0005 to 333-024-0055.¶
(3) "Facility" means:¶
(a) Hospitals and freestanding birthing centers; and¶
(b) Health care clinics and offices where practitioners and other health care professionals provide direct medical care to newborns or infants six months or younger.¶
(4) "Freestanding birthing center" has the meaning given that term in ORS 442.015.¶
(5) "Higher-tier testing" means additional testing performed after screening on the same specimen for the purpose of reducing the number of false-positive results reported for a given disorder.¶
(6) "Hospital" has the meaning given that term in ORS 442.015¶
(7) "Kit" means the specimen collection card (also known as the filter paper collection device,) and the attached demographic form~~, and other items provided by the Oregon State Public Health Laboratory~~ for the purposes of collection ~~or~~and submission of specimens for newborn screening~~ testing~~. ¶
(8) "Newborn screening panel" means the specific medical conditions screened for under OAR 333-024-1070 by the Oregon State Public Health Laboratory or a laboratory under contract with the Oregon Health Authority.¶
(9) "Oregon State Public Health Laboratory" means the laboratory of the Oregon Health Authority that is CLIA

certified, that performs testing pursuant to ORS 431A.750 and 433.285.¶
(10) "PCR" means polymerase chain reaction.¶
(11) "Practitioner" means:¶
(a) A physician licensed under ORS chapter 677;¶
(b) A naturopathic physician licensed under ORS chapter 685;¶
(c) A nurse practitioner or advanced practice registered nurse licensed under ORS chapter 678;¶
(d) A direct entry midwife licensed under ORS chapter 687;¶
(e) A chiropractic physician licensed under ORS chapter 684; and¶
(f) For purposes of OAR 333-024-1020(1) and OAR 333-024-1025(1) only, a licensed or unlicensed individual who takes responsibility for delivery or the health care of an infant born in Oregon; or being none, the individual in Oregon responsible for the health care of a pregnant person prior to the infant being born in Oregon.¶
(12) "Residual specimen" means the part of the specimen that is left after newborn screening testing activities are complete.¶
(13) "Specimen" means a blood specimen obtained from an infant by means of skin-puncture (heel stick) and placed on ~~a~~the speci~~al filter paper kit~~men collection card and allowed to air dry.¶
(14) "These rules" means OAR 333-024-1000 through 333-024-1110.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1030

NOTICE FILED DATE: 09/12/2025

RULE SUMMARY: Amend OAR 333-024-1030

- Amend one month of age to 28 days related to the timing of third collection in premature babies. This change is in alignment with current practices.

CHANGES TO RULE:

333-024-1030
Newborn Screening: Timing for Collecting Specimens
(1) The facility or individual responsible for collecting specimens for newborn screening under OAR 333-024-1020 and OAR 333-024-1025 must collect newborn screening specimens from every infant born in Oregon, and surviving more than two days, unless exempt according to OAR 333-024-1050, as follows:¶
(a) The first specimen shall be collected as soon as possible after 24 hours of age but before 48 hours of age.¶
(b) The second specimen shall be collected between 10 and 14 days of age.¶
(c) Premature (babies born at <34 weeks gestation age) or low birth weight babies (babies born weighing <2000 grams) require an additional specimen collection at approximately ~~one month~~28 days of age. ¶
(d) Additional, repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory and submitted according to the timeline identified by the Oregon State Public Health Laboratory.¶
(2) If an infant under six months of age enters the care of a practitioner and the practitioner is unable to determine whether the infant has been tested in accordance with these rules, a specimen shall be collected and sent to the Oregon State Public Health Laboratory within two weeks of the first visit to the practitioner.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1070

NOTICE FILED DATE: 09/12/2025

RULE SUMMARY: Amend OAR 333-024-1070

- Adds one new condition to the screening panel. Beginning on, November 1, 2025, the newborn bloodspot screening specimens will be tested for Infantile Krabbe Disease.

CHANGES TO RULE:

333-024-1070
Newborn Screening: The Newborn Screening Panel and Methods of Testing
(1) Every properly collected specimen submitted for newborn screening will be tested by the Oregon State Public Health Laboratory or, at the discretion of the Oregon State Public Health Laboratory, another CLIA certified laboratory.¶
(2) Newborn screening specimens will be tested for the medical conditions listed in sections (3) through (11), using the methods listed below. At its discretion, and consistent with CLIA standards, the Oregon State Public Health Laboratory may use an equivalent or better alternative method. ¶
(3) Metabolic Disorders:¶
(a) Organic Acid Disorders. Method: Quantitative measurement of amino acids by tandem mass spectrometry.¶
(A) Propionic acidemia (PA);¶
(B) Methylmalonic acidemia (MMA);¶
(C) Isovaleric acidemia (IVA);¶
(D) 3-methylcrotonyl CoA carboxylase deficiency (3MCC);¶
(E) 3-Hydroxy-3-Methyglutaric Aciduria (HMG);¶
(F) Holocarboxylase Synthase Deficiency;¶
(G) Beta-ketothiolase deficiency (BKT);¶
(H) Glutaric acidemia, Type I (GA-I);¶
(I) Malonic acidemia (MAL);¶
(J) Isobutyrylglycinuria;¶
(K) 2-Methylbutyrylglycinuria;¶
(L) 3-Methylglutaconic aciduria; and¶
(M) 2-methyl-3-hydroxybutyric aciduria.¶
(b) Fatty acid oxidation disorders. Method: Quantitative measurement of acylcarnitines by tandem mass spectrometry.¶
(A) Carnitine uptake defect (CUD);¶
(B) Medium chain acyl-CoA dehydrogenase deficiency (MCAD);¶
(C) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD);¶
(D) Long chain 3 hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);¶
(E) Trifunctional protein deficiency (TFP);¶
(F) Short chain acyl-CoA dehydrogenase deficiency (SCAD);¶
(G) Glutaric acidemia Type II (GA2);¶
(H) Carnitine palmitoyl transferase deficiency, Types I and II (CPT I and CPT II); and¶
(I) Carnitine acylcarnitine translocase deficiency; and¶
(J) X-linked adrenoleukodystrophy (XALD).¶
(c) Amino acid disorders. Method: Quantitative measurement of amino acids by tandem mass spectrometry.¶
(A) Argininosuccinate lyase deficiency ;¶
(B) Citrullinemia, Type I (CIT);¶
(C) Maple syrup urine disease (MSUD);¶
(D) Homocystinuria (HCY);¶
(E) Phenylketonuria (PKU);¶
(F) Tyrosinemia, Types I, II, and III; and¶
(G) Arginemia (ARG).¶
(4) Endocrine disorders:¶
(a) Primary congenital hypothyroidism (CH). Method: Fluorescent immunoassay of thyroxine (T4) or thyroid stimulating hormone (thyrotropin or TSH).¶
(b) Congenital adrenal hyperplasia (CAH). Method: Fluorescent immunoassay of 17-alpha hydroxyprogesterone (17-OHP).¶
(5) Cystic fibrosis. Method: Fluorescent immunoassay of immunoreactive trypsinogen with higher tier molecular analysis for common cystic fibrosis mutations.¶

(6) Biotinidase deficiency. Method: Colorimetric or fluorometric assay for biotinidase activity.¶
(7) Classic Galactosemia. Method: Fluorescent immunoassay for galactose uridyltransferase activity and galactose levels.¶
(8) Sickle cell anemia and other hemoglobin disorders. Method: Electrophoresis and liquid chromatography to detect hemoglobin variants.¶
(9) Severe combined immunodeficiency disease (SCID). Method: PCR to detect T-cell receptor excision circles.¶
(10) Lysosomal storage diseases. Method: Measurement of enzyme activity by tandem mass spectrometry with higher tier testing for specific biochemical marker or molecular analysis of the gene.¶
(a) Pompe (glycogen storage disease Type II);¶
(b) Mucopolysaccharidosis Type I (MPS I);¶
(c) Fabry (alphagalactosidase A deficiency); and,¶
(d) Gaucher (glucocerebrosidase deficiency).¶
(11) Spinal Muscular Atrophy (SMA). Method: PCR to detect deletion of exon 7 in SMN1 gene.¶
(12) Infantile Krabbe Disease (IKD).¶
(13) Newborn screening results may identify other medical conditions that are not listed above. Other medical conditions that are identified during routine newborn screening will be included in a result report as described in OAR 333-024-1080. It is within the discretion of an infant's health care provider and parents or legal guardians to determine what, if any, medical follow-up is needed in these circumstances.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1090

NOTICE FILED DATE: 09/12/2025

RULE SUMMARY: Amend OAR 333-024-1090

- Repeals the use of residual specimens for educational activities because there is no specific educational activity performed in which residual specimens are needed.
- Minor grammatical corrections

CHANGES TO RULE:

333-024-1090
Newborn Screening: Use, Release and Retention of Residual Specimens
(1) Residual specimens may be used by the Oregon State Public Health Laboratory for: ¶
(a) Quality assurance and method development activities as required to maintain CLIA compliance.¶
(b) Program evaluation and quality improvement. ¶
~~(c) Educational activities as required in ORS 433.290. ¶~~
(2) The Oregon State Public Health Laboratory shall only release specimens as follows: ¶
(a) To a third-party laboratory to perform some or all testing described in OAR 333-024-1070. ¶
(b) If required by a court order.¶
(c) To the parent or legal guardian of the infant, or a third party identified by a parent or legal guardian, with a parent or legal guardian's written authorization, according to the Oregon State Public Health Laboratory procedure for requesting specimens. ¶
(3) Specimens may not be released under subsection (2)(c) of this rule within 30 days of the report of the screening results.¶
(4) Specimens submitted to the Oregon State Public Health Laboratory are retained for 12 months after which the specimen is destroyed using a secure method, except as necessary to comply with section (~~1~~2) of this rule. The destruction may occur at any time in the month following the specimen's 12-month retention limit.¶
(5) Specimens retained for longer than 12 months as necessary to comply with section (1) of this rule shall be de-identified by the Oregon State Public Health Laboratory.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)