

Caution:

This consultation draft is intended to facilitate dialogue concerning its contents. Should the decision be made to proceed with the proposal, the comments received during consultation will be considered during the final preparation of the regulation. The content, structure, form and wording of the consultation draft are subject to change as a result of the consultation process and as a result of review, editing and correction by the Office of Legislative Counsel.

CONSULTATION DRAFT

ONTARIO REGULATION

to be made under the

LABORATORY AND SPECIMEN COLLECTION CENTRE LICENSING ACT

Amending O. Reg. 45/22

(GENERAL)

1. (1) Subsection 19 (1) of Ontario Regulation 45/22 is revoked and the following substituted:

Restrictions re prenatal assessments and newborn screening

(1) The owner and the operator of a laboratory shall ensure that no person employed in the laboratory performs a test for Aneuploidies, Fetal Blood Group genotyping (including Fetal RhD) or first-trimester preeclampsia risk under the provincial prenatal screening program unless,

- (a) the laboratory is operated by the Children's Hospital of Eastern Ontario — Ottawa Children's Treatment Centre; or
- (b) the owner or the operator of the laboratory has entered into an agreement with the Children's Hospital of Eastern Ontario — Ottawa Children's Treatment Centre respecting conditions related to the participation of the laboratory in the program.

(2) Subsection 19 (3) of the Regulation is revoked and the following substituted:

(3) The owner and the operator of a laboratory, other than a laboratory described in clause (1) (a) or (b), shall ensure that no person employed in the laboratory performs a test for any of the following if the requisition indicates that the test is for newborn screening:

- 1. Amino acidopathies.
- 2. Biotinidase deficiency.

3. Cystic fibrosis.
4. Endocrinopathies.
5. Fatty acid oxidation defects.
6. Galactosemia.
7. Hemoglobinopathies.
8. Mucopolysaccharidosis type 1.
9. Organic acidemias.
10. Permanent hearing loss.
11. Severe combined immune deficiency.
12. Spinal muscular atrophy.
13. X-ALD (X-linked adrenoleukodystrophy).

2. The Regulation is amended by adding the following section:

Midwives

25.1 (1) A member of the Ontario College of Midwives of Ontario is exempt from sections 9 to 16 of the Act and from this Regulation with respect to performing one or more point-of-care tests listed in subsection (2) in the course of their midwifery practice.

(2) The point-of-care tests mentioned in subsection (1) are as follows:

1. Amniotic swab.
2. Blood Group — ABO and RhD.
3. Ferning test.
4. Glucose.
5. Hemoglobin test.
6. Pregnancy test.
7. Strep B rapid screen.

8. Urine dipstick.

3. (1) Paragraph 26 of Schedule 1 to the Regulation is revoked and the following substituted:

26. Aspartate transaminase (AST).

(2) Paragraph 29 of Schedule 1 to the Regulation is revoked and the following substituted:

29. Blood Group — ABO and RhD.

(3) Paragraph 68 of Schedule 1 to the Regulation is revoked and the following substituted:

68. Gamma-glutamyl transferase (GGT).

(4) Paragraph 84 of Schedule 1 to the Regulation is revoked and the following substituted:

84. Lactate dehydrogenase (LDH), total.

(5) Paragraph 98 of Schedule 1 to the Regulation is revoked and the following substituted:

98. Phosphatase, alkaline (ALP).

(6) Schedule 1 to the Regulation is amended by adding the following paragraph:

114.1 T-4, free absolute.

(7) Paragraph 120 of Schedule 1 to the Regulation is revoked.

4. Schedule 2 to the Regulation is revoked and the following substituted:

SCHEDULE 2
TESTS — REQUISITION BY MIDWIFE, SECTION 18

1. Alanine transaminase (ALT).

2. Albumin quantitative.

3. Alphafetoprotein screen.

4. Antibody identification.
5. Antibody screen.
6. Aspartate transaminase (AST).
7. Bile acid breath test.
8. Bile acid total and fractionation.
9. Bilirubin — conjugated.
10. Bilirubin — total.
11. Bilirubin — unconjugated.
12. Blood culture (including aerobic, anaerobic, subcultures, smears).
13. Blood Group — ABO and RhD.
14. Blood Group — per antigen.
15. Carrier screening (hemoglobinopathy, Tay-Sachs, Ashkenazi Jewish screening panel).
16. Cervicovaginal specimens.
17. Chlamydia.
18. Chlamydia by Nucleic Acid Amplification Test (NAAT).
19. Complete blood count (any method).
20. Creatinine, including estimated glomerular filtration rate (eGFR).
21. Crossmatch per unit of blood.
22. Culture — cervical, vaginal (includes GC).
23. Culture — other swabs or pus.
24. Culture — urine.
25. Cytomegalovirus (CMV).

26. Direct anti-human globulin test.
27. Estriol.
28. Fetal fibronectin.
29. Gamma-glutamyl transferase (GGT).
30. Glucose.
31. Glucose tolerance test in pregnancy.
32. Glycosylated hemoglobin — HbA1c.
33. Gonorrhea by Nucleic Acid Amplification Test (NAAT).
34. Hemoglobin electrophoresis or chromatography to include Hb A2 (Hemoglobin A2) fraction.
35. Hepatitis associated antigen or antibody immunoassay (for a specific marker).
36. Human Chorionic Gonadotropin.
37. Inhibin.
38. Kleihauer.
39. Lactate dehydrogenase (LDH), total.
40. Lactate (Fetal Scalp Lactate (FSL)).
41. Newborn screening test for amino acidopathies, fatty acid oxidation defects, organic acidemias, endocrinopathies, hemoglobinopathies, biotinidase deficiency, galactosemia, cystic fibrosis, severe combined immune deficiency, permanent hearing loss risk, mucopolysaccharidosis type I or spinal muscular atrophy.
42. Non-invasive prenatal testing (NIPT).
43. pCO₂, pO₂ and pH in combination.
44. Phosphatase, alkaline (ALP).
45. Placental growth factor — A.

46. Placental growth factor — B.
47. Polymerase Chain Reaction (PCR), urine testing and serology for Zika virus.
48. Potassium.
49. Protein, total.
50. Protein, total (24-hour urine, total protein).
51. Pregnancy-associated plasma protein A (PAPP-A).
52. Pregnancy test.
53. Serology HIV antibody.
54. Serum ferritin.
55. Serum folate.
56. Sickle cell solubility test (screen).
57. Smear only, Gram or Papanicolaou stain.
58. Strep B rapid screen.
59. T-3, total (triiodothyronine).
60. T-4, free absolute.
61. T-4, total.
62. Toxoplasmosis.
63. TSH (thyroid stimulating hormone).
64. Uric acid (Urate).
65. Urinalysis — routine (includes microscopic).
66. Varicella zoster virus (VZV).
67. Venereal Disease Research Laboratory (VDRL) test.

68. Virus antibodies — hemagglutination inhibition or ELISA technique (Rubella).
69. Virus isolation.
70. Vitamin B12.
71. Vitamin D, 25-hydroxy.
72. Wet preparation (for fungus, trichomonas, parasites).

Commencement

5. [Commencement]