LABORATORY REVIEW TOOL

AGENCY: REVIEWER:

ADMINISTRATOR: LAB DIRECTOR:

PARTICIPANTS:

DATE OF REVIEW (mm/dd/yyyy): DATE OF REPORT (mm/dd/yyyy):

Criteria for Compliance	Compliant Y	Compliant N	Comments/Documentation/Explanation/Timelines
I. LABORATORY LEVEL			
☐ **Waived** 42CRF493.15(c) ☐ **Provider Performed Microscopy (PPM)** 42CFR493.47	Laboratory locations covered under this certificate (including any school-based health centers): 1.		
A. There is a current, valid CLIA certificate. 42CRF493.3(a)(1)	☐	☐	
B. The certificate is displayed at all times in a prominent place in the laboratory. OAR 333-024-0012 (6)	☐	☐	
C. Tests performed are within the scope of the certificate. Waived - 42CFR493.15(c); PPM - 42CFR493.47	☐	☐	
D. A clinical laboratory director is designated. Waived - 42CFR493.35(c)(3)(iii); PPM - 42CFR493.1355	☐	☐	
1. The laboratory director must be qualified to manage and direct the laboratory personnel (and performance of PPM procedures if applicable). 42CFR493.1357	☐	☐	
2. The laboratory director meets one of the following requirements: 42CFR493.2 ☐ Is a **physician** ☐ Is a **midlevel practitioner** (midwife, nurse practitioner, or physician assistant, authorized by a state to practice independently in the			

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state in which the laboratory is located); or ☐ is a **dentist**			
II. POLICIES, PROCEDURES AND STAFF COMPETENCIES			
A. Lab policies and procedure manual has been developed, with each policy and procedure approved, signed and dated by the lab director. 42CFR493.1251	☐	☐	**PPM ONLY**
B. Lab process adheres to manufacturer guidelines. Products currently used are matched to those in procedure manual. Waived 42CFR493.15(e)(1) PPM 42CFR493.1251(a-c)	☐	☐	See the table at the end of the tool.
C. The lab follows established written polices and procedures for specimen submission, handling, and referral. 42CFR493.1242	☐	☐	**PPM ONLY**
D. A system is in place to identify each individual performing a test. 42CFR493.1283(4)	☐	☐	**PPM ONLY**
E. Annual personnel competency testing is documented for all individuals performing laboratory tests, including physicians and mid-level practitioners. 42CFR493.1235	☐	☐	**PPM ONLY**
F. At least twice annually the laboratory must verify the accuracy of any test procedure it performs. 42CFR493.1236 (c)(1)	☐	☐	**PPM ONLY**
G. A written quality assurance plan exists. 42CFR493.1200(a-c)	☐	☐	**PPM ONLY**
1. Plan includes chart reviews for pre-analytic, analytic, and post-analytic phases of laboratory testing. 42CFR493.1200(a)	☐	☐	**PPM ONLY**
2. There is a written order for test; results are documented and signed off by provider. 42CFR1493.1241(a-b), ORS 438.430 (1)	☐	☐	
H. A system is in place to identify and track all laboratory tests, including pap tests and those sent to a reference laboratory. 42CFR493.1242, 42CFR493.1291(a)	☐	☐	**PPM ONLY**

1. Confidentiality of results is assured. 42CFR493.1231	☐	☐	**PPM ONLY; Waived: HIPAA**
2. Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test. 42CFR493.1291(f), ORS 438.430 (2)	☐	☐	
I. Pertinent "reference intervals" or "normal" values are available to the authorized person who ordered the tests and the individual responsible for using the test results. 42CFR493.1291(d)	☐	☐	**PPM ONLY**
1. Reference manual, from any reference laboratory used, is readily available in the laboratory.	☐	☐	
2. A written policy outlines what action is to be taken, by whom, in the event of critical values. 42CFR493.1251(b)(13)	☐	☐	**PPM ONLY**
3. The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. 42CFR493.1291(g)	☐	☐	**PPM ONLY**
4. Critical values are posted	☐	☐	
J. Protocols for equipment monitoring and calibration are in laboratory manual, and written records of these procedures are available. 42CFR493.1254, 42CFR493.1255	☐	☐	**PPM ONLY**
1. Where maintenance and function check protocols are not provided by the manufacturer: (i) there is a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting. (ii) There is a record of the maintenance activities, including background and baseline checks. 42CRF493.1254(b)	☐	☐	**Microscopes (PPM Only)**

2. Hemocue & glucose meters, daily or manufacturer guidelines 42CRF493.15(e)	☐	☐	
3. Refrigerator temperature must be monitored and documented. 42CFR493.1252(b)	☐	☐	**PPM ONLY**

Waived or PPM* Test Type	Performed	Product Name	Policy & Procedure in lab manual	Package insert available	QC procedure in place	Proficiency testing complete	Comments
Dipstick or tablet Reagent Urinalysis (non-automated) for the following: Bilirubin; Glucose; Hemoglobin; Ketone; Leukocytes; Nitrite; pH; Protein; Specific gravity; & Urobilinogen	☐		☐	☐	☐	☐	
Fecal occult blood	☐		☐	☐	☐	☐	
Ovulation tests – visual color comparison tests for human luteinizing hormone	☐		☐	☐	☐	☐	
Urine pregnancy tests – visual comparison tests	☐		☐	☐	☐	☐	
Erythrocyte sedimentation rate – non automated	☐		☐	☐	☐	☐	
Hemoglobin – copper sulfate – non automated	☐		☐	☐	☐	☐	
Spun microhematocrit	☐		☐	☐	☐	☐	
Blood Glucose by glucose monitoring devices cleared by the FDA specifically for home use	☐		☐	☐	☐	☐	
Hemoglobin by single analyte instruments, providing direct measurement and readout	☐		☐	☐	☐	☐	
Rapid HIV	☐		☐	☐	☐	☐	
Wet mounts*, including preparations of vaginal, cervical, or skin specimens	☐		☐	☐	☐	☐	
KOH preparations*	☐		☐	☐	☐	☐	
Urine microscopy*	☐		☐	☐	☐	☐	
Others: (list)	☐		☐	☐	☐	☐	

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