

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0656873	(X3) Date Survey Completed 09/24/2024
Name of Provider or Supplier Corvallis Clinic, Pc Laboratory,The	Street Address, City, State 3680 Nw Samaritan Dr, Asbury Bldg 2nd Floor, Corvallis, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) procedure (SOP) and interview with the laboratory's three (3) Technical Supervisors (TS) and one (1) Technical Consultant (TC), the laboratory failed to establish and follow a current QA Standard Operating Procedure (SOP). Findings include: 1. Upon review of the QA SOP in the procedure manual presented for review during survey, the SOP stated the lab staff and the Laboratory Director (LD) would all meet quarterly to discuss QA. 2. When asked for evidence of these meetings for 2023 and 2024, none could be produced. 3. Interview at 2:30 pm, with three (3) TS's and one (1) TC confirmed that the QA procedure in the procedure manual was outdated and not being followed as written, using the data collection forms in the SOP. 4. The laboratory reports performing 796,069 moderate and high complexity assays annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:
 Upon review of the laboratory's procedure for Vaginal Wet mounts and Potassium Hydroxide (KOH) mounts and interview with the Microbiology Technical Supervisor (TS), it was revealed that the laboratory did not have a policy or procedure specific to the providers performing these assays in the Obstetrics department of the facility. Findings include: 1. Upon request for the laboratory's Vaginal Wet Mount and KOH procedure, it was revealed that the procedure produced pertained to laboratory staff only and not other providers performing these assays outside of the laboratory in the Obstetrics Department of this facility that are under this CLIA certificate. 2. Upon review of competency assessment records of the three providers performing Vaginal Wet Mounts and KOH mounts, it was revealed that zero (0) out of three (3) providers were in compliance with competency assessment assignments. 3. Interview with the Microbiology TS on 09/25/2024 at 12:30 pm revealed that no procedure specific to the three (3) providers performing Vaginal Wet mounts, Fern testing and KOH mounts, including the frequency and expectation of competency assessment participation. During the same interview with the TS, it was revealed that the three (3) providers had recently suggested patient self collected vaginal swabs for these assays, so a policy/procedure for patient self collected vaginal swabs was requested. None could be produced. The Microbiology TS confirmed the laboratory had no knowledge of a procedure for patient self collected vaginal swabs. 4. The number of Vaginal Wet mounts and KOH mounts performed by these three (3) providers could not be determined. 5. See D6012

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
 Based on review of laboratory testing personnel records and interview with three (3) Technical Supervisors (TS) and one (1) Technical Consultant, the Laboratory Director (LD) failed to ensure that an approved written and current list of all laboratory personnel performing any or all three (3) phases of laboratory testing and competency assessment was signed, approved and available for review. Findings include: 1. Upon request for a current list of all testing personnel (TP) and technical laboratory personnel performing pre-analytical, analytical and post analytical testing, none could be produced. 2. Interview with the three (3) TS's and one (1) TC at 1030 on 09/25 /2024 confirmed that there was no current LD approved written document designating who can do what in this laboratory. 3. The laboratory reports performing 796,069 moderate and high complexity assays annually.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assurance (QA) plan and interview with laboratory three (3) Technical Supervisors (TS) and one (1) Technical Consultant (TC), the Laboratory Director (LD) failed to ensure a current signed and approved QA plan was in place. Findings include: 1. See D5291

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of competency assessment assigned to three (3) providers performing Potassium Hydroxide (KOH) Vaginal wet mounts and FERN testing in the Obstetrics department, the Laboratory Director (LD) failed to ensure that the providers complied with the requisite competency assessments assigned to them for 2023 and 2024. Findings include: 1. Review of the MTS on line training assigned to each of the providers revealed the following: Provider # 1 Assignments for dates back to 01/1/2020 up to date of survey revealed that provider # 1 performed 0 out of 10 competency assignments for Vaginal Wet Prep. Provider # 1 Assignments for dates back to 07/1/2021 up to date of survey revealed that provider # 1 performed 0 out of 7 competency assignments for Vaginal KOH prep. NO FERN competency assignments for this provider. Provider # 2 Assignments for dates back to 01/1/2020 up to date of survey revealed that provider # 2 performed 1 out of 8 competency assignments for Vaginal Wet Prep. Provider # 2 Assignments for dates back to 01/1/2021, up to date of survey revealed that provider # 2 performed 1 out of 8 competency assignments for Vaginal KOH prep. Provider # 2 Assignments for dates back to 01/1/2020, up to date of survey revealed that provider # 2 performed 3 out of 10 competency assignments for the FERN test. Provider # 3 Assignments for dates back to 01/1/2021 up to date of survey revealed that provider # 3 performed 0 out of 8 competency assignments for Vaginal Wet Prep. Provider # 3 Assignments for dates back to 01/1/2021 up to date of survey revealed that provider # 3 performed 0 out of 8 competency assignments for Vaginal KOH prep. Provider # 3 Assignments for dates back to 01/1/2021, up to date of survey revealed that provider # 3 performed 0 out of 8 competency assignments for the FERN test. 2. Interview with the the Technical Supervisors (3) confirmed that the three (3) Obstetrics providers did not attempt or complete the assigned competency assessments for Vagina Wet Preps, Vaginal KOH mounts or Fern testig, assigned twice per year on the MTS on line training site. 3. Request for test number of the three (3) assays being performed by the three (3) providers annually, none could be confirmed as providers do not always log these tests done bedside, per nursing personnel on the floor An estimate was given at four (4) per month.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel competency records provided during survey and interview with laboratory technical staff, the Laboratory Director (LD) failed to specify in writing, the duties of each supervisor and testing personnel. Findings include: 1. Request for a current list of duties and responsibilities of each person (name, not title) performing pre-analytic, analytic, and post analytic activities in this laboratory, none could be produced. 2. During summation for survey ending 09/25 /2024, the LD confirmed there was no current list of duties and testing allowed for each laboratory staff member (identified by name and not title) at this time. 3. The laboratory reports performing 796,069 moderate and high complexity tests annually.