Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2327250	04/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Women's Care Laboratory At Chase Gardens	360 South Garden Way Ste 290, Eugene, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with the Technical Consultant (TC), the laboratory failed to perform competency assessment of personnel that hold a federal title, in this case, the TC. Findings include: 1. Upon request for the procedure for competency assessment of the TC's federal duties, by the Laboratory Director (LD), none could be produced. 2. Upon request for a current written competency assessment for the federal duties assigned to theTC, by the Laboratory Director (LD), none could be produced. 3. Interview with the TC confirmed that he had not been assessed for competency related to his federal duties listed in his job description, by the LD. 4. The laboratory reports performing 1500 moderately complex tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records for Urinalysis and interview with the Technical Consultant (TC), the laboratory failed to ensure the performance of and

	documentation of QC for urinalysis by eleven (11) testing personnel (TP) was performed and documented correctly. Findings include: 1. Upon review of the QC records and the manufacturers package insert, kept by the laboratory, for November 2025 through April 7, 2026, it was revealed that the referrance rage for pH Level 1 from Quantimetrix, lot # 256321 exp. 09/30/2026 was 5.0 - 6.5. 2. Upon further review of the QC logs, it was noted that the referrange for pH Level 1 was recorded as follows: a. November 2025 Written log says pH 6.0 - 7.5 Lab recorded 20 days of QC, which read pH 5.0 - 5.5 b. December 2025 Written log says pH 6.0 - 7.5 Lab recorded 22 days of QC, which read pH 5.0 - 5.5 c. January 2026 Written log says pH 6.0 - 7.5 Lab recorded 20 days of QC, which read pH 5.0 - 5.5 d. February 2026 Written log says pH 5.0 - 7.5, the correct range is 5.0 - 6.5 per package insert e. March 2026 Unable to determine as the reference range for pH Level 1 QC has been written through on the QC log. f. April 2026 (until 4/7/2026) Written log says pH 6.0 - 7.5 Lab recorded 5 days of Level 1 QC, which read pH 5.5 3. Review of these QC logs, for evidence of TC review, failed to yield any evidence of review by the TC (November 2025 - April 7th, 2026). 4. Interview with the TC at 2:30 pm confirmed that he did not review the Urinalysis QC records for this lab since November 2025. 5. The laboratory reports performing 1000 moderate complexityurinalysis's annually.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, maintenance records for the Clinitek Status analyzer and interview with the Technical Consultant (TC), the laboratory testing personnel (TP) failed to adhere to the QC and maintenance requirements for performing urinalysis. Findings include: 1. Upon review of the urinalysis QC records for 11/1/2025 - April 7, 2026, it was noted that the reference range for Quantimetrix QC Level 1 control lot #256321 exp. 09/30/2026, had been incorrectly entered on the log as the reference range for pH for all 6 months. 2. Identification of each individual TP was not able to be done as some TP did not record their initials and there was no signature key provided. 3. Upon request for calibratoin requirements and maintenance records for the Clinitek Status Urinalysis instrument, it was noted that the manufacturer recommends cleaning the calibration white bar week to ensure proper instrumentfunction, none could be produced. 4. Interview with the TC at 2:30 pm confirmed these findings. 5. The laboratory reports performing 1000 moderate complexity urinalysis tests annually.