Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0963720	03/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Curry Medical Center Laboratory	500 5th St, Brookings, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of the Individual Quality Control Plans (IQCP's) submitted for review during survey, also post survey via email and interview with the Technical Supervisor (TS) and General Supervisor (GS), TS/GS #1, the laboratory failed to ensure that the IQCP's in place at this facility included all three (3) required parts of an IQCP and were approved by the Laboratory Director (LD). Findings include: 1. According to CFR 493.1256(d), an IQCP must contain three (3) parts which include a Risk Assessment (RA), a Quality Control Plan (QCP) and a Quality Assessment (QA) part. 2. Upon initial review of the IQCP's submitted for review during survey, it was revealed that the laboratory had hired a contract company to initiate the creation of the IQCP's for this facility. 3. The name of the contracted company of record was "QC made EZ - IQCP E-Optimizer". None of the seven (7) IQCP's reviewed for this facility revealed the location of this contracted company, so location or other information regarding this company was unknown. 4. Further investigation post survey via a search of the internet revealed the company "QC made EZ - IQCP E-Optimizer" states their services as follows: "This IQCP Program provides the tools necessary to perform risk assessments and develop QC plans unique to your

	laboratory and offers your laboratory flexibility to choose the tools that will best suit your needs". There was no easily viewed information about the QA part of an IQCP. 5. Upon review of seven (7) IQCP's for this site, all of which were composed by the contracted company "QC made EZ - IQCP E-Optimizer", the following was revealed: a. The OSOM Sekisui Human Chorionic Gonadotropin (HcG) combo IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service, lacked a QCP and a QA part for this IQCP. Established date not available. It was last reviewed 6/5 /2017. b. Blood Gas analysis using the iSTAT instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11/28/2022, lacked a QCP, a QA part for this IQCP and a signed and dated approval page by the LD. c. The Basic Metabolic Panel (BMP) analysis using the iSTAT instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 12 12 2022, lacked a QCP, a QA section of this IQCP and a signed and dated approval page by the LD. d. The Streptococcus pyogenes IQCP (termed Strep A) assay using the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11/1/2023, lacked a QCP and a QA part for this IQCP. Last reviewed by the LD 12/14/2023. e. The IQCP termed "4 plex", which included testing for four (4) different viral organisms including SAR-COV 2 (COVID), Influenza A & B, and Respiratory Syncytial virus (RSV) using the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11 /22/2023, lacked a QCP and a QA part for this IQCP. Last reviewed and approved by the LD 12/14/2023. f. The IQCP termed SARS COV 2 plus, using the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11 16 2023, lacked a QCP and a QA part for this IQCP. Last reviewed and approved by the LD 2/14/2023. g. The Med-Tox instrument IQCP, for detection of drugs of abuse, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established date unavailable. The date of last review by the LD was 05/07/2018. There was no evidence of QCP review or QA documentation for review while on site and as stated in the QCP and QA part of this IQCP since 2018, nor evidence submitted for review via emails post survey 03/18/2025 and 03/19/2025. 6. Interview with TS/GS #1 at 3:00 pm during survey and also post survey via email 03/18/2025, 03/19/2025 and 03/20/2025, confirmed the above deficient practices. 7. The laboratory reports performing the following tests annually for those tests listed above. SARS - COVID 2 796 assays annually 4 Plex for four viral infectious agents including COVID, Influenza A&B and RSV, 1408 assays annually. Strep A 690 assays annually. iStat Basic Metabolic Panel 12 assays annually iStat Blood Gases 5 assays annually Medtox panel for drugs of abuse 513 assays annually HCG serum 141 assays annually
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the patient test report for a complete blood count (CBC) reference ranges for Red Blood Cell (RBC's) count and Platelet (Plt) count, generated by the Beckman Coulter DxH 600 hematology analyzer, and review of the reference ranges for the same analyzer and assay on the LIS and interview with the Technical Supervisor (TS), also the General Supervisor (GS), TS/GS #1 for this site, it was

	revealed that the reference ranges in the laboratory information system (LIS) differed from the reference ranges on the patient report printed for review during survey. Findings include: 1. Upon request for a patient report for CBC, one was produced and reviewed by this surveyor and a surveyor in training. 2. Upon request for access to the LIS and it's record of reference values for a CBC, the TS/GS #1 brought up the screen for review on her laptop. The surveyor in training then read the reference ranges on the screen and I compared them to the printed patient report I was given by the TS/GS #1. During this review, it was revealed that the two (2) systems did not agree for current reference ranges for RBC's and Platelets on the patient report and in the LIS. 3. The printed patient report indicated reference ranges for the RBC count and Plt count for adult males (was the patient type on the patient repot), using the Coulter DxH 600 hematology instrument was: RBC's = 4.5 - 11.0 K/uL Plt's = 142 - 424 K/uL The LIS screen presented for review during survey revealed the reference ranges for these two (2) analytes at time of survey to be: RBC's = 3.9 - 12.1 K/uL Plt's = 80 - 451 K/uL 4. Interview with the TS/GS # 1 at 1230 pm confirmed the discrepancy in the reference range for RBC's and Plt's on the patient report and the LIS as presented during survey. 5. The laboratory reports performing 58,548 hematology assays annually.