Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0628373	12/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Harney District Hospital Lab	557 W Washington St, Burns, 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 personnel interview and document review on December 13, 2023 at 10:10 am, the laboratory failed to establish and follow written policies and procedures for personnel competency assessments, including remedial training or continuing education needs, that included all the elements listed at 42 CFR 493.1451(b)(8). Findings included: a. It was the practice of the laboratory to include quizzes in initial testing personnel competency assessments. A review of initial testing personnel competency assessments indicated the following: i. Testing Personnel 3's (TP-3's) Cepheid quiz was upgraded. ii. TP-5's "moderate complexity" initial quiz was scored as "failed." iii. Only 1 of 5 TP had a "moderate complexity" quiz. b. Interview with the Technical supervisor (TS) confirmed that the laboratory did not have written policies and procedures for conducting laboratory personnel competency assessments. c. According to laboratory records, the laboratory performed approximately 171,000 tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on interview with the laboratory director (LD) and document review on December 13, 2023 at 3:00 pm, at least twice annually, the laboratory failed to verify the accuracy of C-Reactive Protein (CRP) and measured total iron-binding capacity (TIBC), tests or procedures it performed that is not included in subpart I of this part, in 2023. Findings include: a. It is the laboratory's practice to enroll in CRP and TIBC proficiency testing (PT) to meet the requirement at 42 CFR 493.1236(c)(1). b. A review of the laboratory's 2023 PT records showed that the laboratory received unsatisfactory CRP and TIBC PT test scores (i.e., obtain a minimum proficiency test score of 80%) in two consecutive proficiency testing events or two out of three consecutive proficiency testing events. Year Event Score Analyte 2023 1st 50% CRP 2023 2nd 50% CRP 2023 1st 60% TIBC 2023 2nd 40% TIBC c. Interview with the LD confirmed these findings. d. The laboratory performed and reported approximately 900 patient CRP and TIBC test results annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and postanalytic systems quality assessment policies and procedures record review on December 13, 2023 at 10:30 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the general laboratory systems specified in 493.1231 through 493.1236. Findings included: a. As confirmed by laboratory personnel, the laboratory maintained no written policies and procedures detailing the laboratory's quality assessment mechanisms to monitor, assess and, when indicated, correct problems identified in the laboratory's general laboratory systems. b. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens annually
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on testing personnel interview and specimen collection policies and procedures record review on December 13, 2023 at 10:00 am, the laboratory failed to establish written policies and procedures for the collection of blood specimens. Findings included: a. It was the practice of the laboratory to collect patient blood specimens using routine phlebotomy procedures. b. As confirmed by testing personnel, the

	laboratory maintained no written policies and procedures detailing the laboratory's phlebotomy protocols. c. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) 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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and analytic systems quality assessment policies and procedures record review on December 13, 2023 at 10:15 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems specified in 493.1241 through 493.1242. Findings included: a. As confirmed by laboratory personnel, the laboratory maintained no written policies and procedures detailing the laboratory's quality assessment mechanisms to monitor, assess and, when indicated, correct problems identified in the laboratory's preanalytic systems. b. For example, the laboratory maintained no written policies and procedures establishing the laboratory's preanalytic systems quality assessment protocol to ensure written policies and procedures for the collection of blood specimens were established. See D5311. c. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: 1. Based on testing personnel interview and hematology written policies and procedures record review on December 13, 2023 at 11:30 am, the laboratory failed to have a procedure manual that included a hematology quality control procedure.

	Finding included: a. It was the practice of the laboratory to perform and report patient complete blood counts (CBCs) using the Sysmex XN-1000 instrument. b. To meet the CLIA requirement at 42 CFR 493.1256(c)(10)(ii), when the laboratory changed lots of quality control materials used to monitor patient testing using the Sysmex XN-1000, the laboratory ran the current lot of quality control materials concurrent with the new lot of quality control materials for seven (7) consecutive days before using the new lot of quality control materials independently. c. As confirmed by testing personnel, the laboratory maintained no written policies and procedures detailing this quality control activity. d. According to laboratory records, the laboratory performed and reported approximately 5,100 patient CBCs annually. 2. Based on testing personnel interview and coagulation written policies and procedures record review on December 13, 2023 at 11:45, the laboratory failed to have a procedure manual that included a coagulation quality control procedure. Finding included: a. It was the practice of the laboratory to perform and report patient coagulation tests using the Sysmex VS-600 instrument. b. With each new lot of coagulation quality control materials, the laboratory established the statistical parameters for the unassayed coagulation quality control materials to be used before using the quality control materials to monitor patient coagulation tests using the Sysmex CA-6000 instrument. c. As confirmed by testing personnel, the laboratory maintained no written policies and procedures detailing the protocol for established the statistical parameters for unassayed coagulation quality control materials. d. According to laboratory records, the laboratory performed and reported approximately 650 patient coagulation tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on testing personnel interview and specimen collection policies and procedures record review on December 13, 2023 at 10:00 am, the laboratory failed to have a patient urine specimen collection procedure that was approved, signed, and dated by the current laboratory director before use. Findings included: a. It was the practice of the laboratory to provide patients with instructions titled "CCMS Urine Instructions" for the collect of patient urine specimens. b. As confirmed by testing personnel, the laboratory maintained no written documentation that the "CCMS Urine Instructions" had been approved, signed, and dated by the current laboratory director before use. c. According to laboratory records, the laboratory performed approximately 1,400 tests on patient urine specimens annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on testing personnel interview and microbiology instrument maintenance log record review on December 13, 2023 at 10:45 am, the laboratory failed to perform and

	document instrument maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the Cepheid GeneXpert Dx instrument. Findings included: a. In microbiology, it was the practice of the laboratory to test patient specimens using the Cepheid GeneXpert Dx test system and instrument for C. difficile, Flu A and Flu B, Group B Strep, Neisseria gonorrhoeae, RSV, SARS-CoV-2, and trichomoniasis. b. For the Cepheid GeneXpert Dx instrument, the manufacturer required the performance of maintenance that included the cleaning of the plunger rod, cartridge bays, and instrument and hub surfaces every three months. c. According to laboratory records and as confirmed by testing personnel, from July 2023 to November 2023, the laboratory had no records to indicate that the laboratory had performed the manufacturer's required every 3 month maintenance on the Cepheid GeneXpert Dx instrument. d. According to laboratory records, the laboratory tested and reported approximately 1000 patient C. difficile, Flu A and Flu B, Group B Strep, Neisseria gonorrhoeae, RSV, SARS-CoV-2, and trichomoniasis tests annually.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on testing personnel interview and microbiology testing record review on December 13, 2023 at 11:00 am, the laboratory failed to maintain an information or record system that included the identity of the personnel who performed tests using the Cepheid GeneXpert Dx instrument. Findings included: a. In microbiology, it was the practice of the laboratory to test patient specimens using the Cepheid GeneXpert Dx test system and instrument for C. difficile, Flu A and Flu B, Group B Strep, Neisseria gonorrhoeae, RSV, SARS-CoV-2, and trichomoniasis. b. As confirmed by testing personnel, the laboratory maintained no records that would indicate the identity of the personnel who performed testing using the Cepheid GeneXpert Dx instrument. d. According to laboratory records, the laboratory tested and reported approximately 1000 patient C. difficile, Flu A and Flu B, Group B Strep, Neisseria gonorrhoeae, RSV, SARS-CoV-2, and trichomoniasis tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and analytic systems quality assessment policies and procedures record review on December 13, 2023 at 10:15 am, the laboratory failed to establish written policies and procedures for an ongoing

	mechanism to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings included: a. As confirmed by laboratory personnel, the laboratory maintained no written policies and procedures detailing the laboratory's quality assessment mechanisms to monitor, assess and, when indicated, correct problems identified in the laboratory's analytic systems. b. For example, the laboratory maintained no written policies and procedures establishing the laboratory's analytic systems quality assessment protocol to ensure: i. Written policies and procedures for patient urine specimen collection were approved, signed, and dated by the current laboratory director before use. See D5407. ii. The laboratory performed and documented instrument maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the Cepheid GeneXpert Dx instrument. See D5429. iii. The laboratory's record titled "GeneXpert Dx Maintenance Log" indicated that the logs are to be reviewed monthly. The laboratory maintained no documentation to indicate that these logs had been reviewed from June 2023 to November 2023. ix. The laboratory maintained an information or record system that included the identity of the personnel who performed tests using the Cepheid GeneXpert Dx instrument. See D5787. v. The laboratory's record titled "Access2 Maintenance Log" indicated that the logs are to be reviewed monthly. The laboratory maintained no documentation to indicate that these logs had been reviewed in October and November 2023. vi. The laboratory's record titled "Sysmex CA-600 Maintenance Log" indicated that the logs are to be reviewed monthly. The laboratory maintained no documentation to indicate that these logs had been reviewed from June 2023 to November 2023. vii. The laboratory's record titled "Sysmex XN-1000 Maintenance Log" indicated that the logs are to be reviewed monthly. The laboratory maintained no documentation to indicate that these logs had been reviewed from June 2023 to November 2023. viii. The laboratory established written protocols that included a hematology quality control procedure. See D5403. ix. The laboratory established written protocols that included a coagulation quality control procedure. D5403. x. The laboratory's quality control records for Sysmex XN-1000 indicated that the logs are to be reviewed monthly. The laboratory maintained no documentation to indicate that these logs had been reviewed from June 2023 to November 2023. c. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) 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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and postanalytic systems quality assessment policies and procedures record review on December 13, 2023 at 10:15 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings included: a. As confirmed by laboratory personnel, the laboratory maintained no written policies and procedures detailing the laboratory's quality assessment mechanisms to monitor, assess and, when indicated, correct problems identified in the laboratory's postanalytic systems. b. For example, the laboratory maintained no written policies and procedures establishing the laboratory's postanalytic systems quality assessment protocol to ensure all patient

	tests requested were performed and reported timely. According to testing personnel, at the end of every shift, testing personnel informed testing personnel on the following shift what patient tests were pending or needed further testing before test results could be reported. c. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens 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 laboratory personnel interviews and quality assessment record review on December 13, 2023, the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings included: a. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the general laboratory systems specified in 493.1231 through 493.1236. See D5291. b. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems specified in 493.1241 through 493.1242. See D5391. c. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. See D5791 d. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. See D5891. e. According to laboratory records, the laboratory performed approximately 171,000 tests on patient blood specimens annually.