Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0628373	06/03/2022
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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's policies and procedures and discussion with staff the laboratory failed to ensure that complaint investigations, discrepant patients results, quality control and calibration issues were monitored and evaluated and rectified. Refer to D5205, D5211, D5291 and D5293.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures and interview with the Laboratory Director (LD) and Laboratory Manager (LM) on 06/03/2022 @ 10:30 AM the laboratory failed to implement their complaint investigation protocol. Findings include: 1. There were twenty seven (27) management and adverse events reported using the Patient Incident Form that was reviewed from 12/21/2021 to 05/13/2022.

	The specialties involved were 10 in Chemistry, 3 in Urinalysis, 2 in Hematology, 1 in Coagulation, and 3 in Bacteriology. 2. Nineteen (19) of the adverse events were from testing personnel who lacked training and oversight, that resulted in the test not being perform, delayed in testing, or incorrect patients results. There were no follow through to determine root cause and what actions were taken to rectify the lack of training and oversight for testing personnel. 3 The Lab Director and staff concurred with these findings on 06/03/2022 @ 10:30.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records from the American Association of Bioanalyst (AAB) the laboratory failed to achieve acceptable test scores for the sub-specialties in Bacteriology, Endocrinology and Routine Chemistry for the 1st event 2022.. Findings include: 1. AAB 1st event 2022 Virology - 60% 2. AAB 1st event 2022 Free TY - 60% 3. AAB 1st event 2022 Routine Chemistry a) Amylase - 60% b) Total Cholesterol - 0% c) Cholesterol HDL - 60% d) Creatinine kinase total- 60% e) CK Isoenzyme - 60% f) Iron total - 60% g) LDH total - 60% h) Magnesium - 60% i) Triglyceride - 0% j) Uric Acid - 0% 4. Documentation for failure was cited as clerical errors both in running the specimens and entering results in the AAB system. 5. Lab Director and staff concurred with these findings 06/03/2022 @ 10:30.
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 review of the laboratory's policies and procedures and interview with the Laboratory Director and Laboratory Manager on 06/03/2022 @ 10:30AM the laboratory failed to document corrective actions for issues within the laboratory. Findings include: 1. The laboratory does not have a Quality Assurance Plan procedure at the time of survey. 2. Review of twenty seven (27) management and adverse events reported using the Patient Incident Form from 12/21/2021 to 05/13/2022, the laboratory failed to document corrective actions of these (27) management and adverse events. 3. The Lab Director and staff concurred with these findings on 06/03 /2022 @ 10:30.AM.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general

	laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the Laboratory Director and Laboratory Manager on 06/03/2022 @ 10:30AM the laboratory failed to document corrective actions for issues within the laboratory. Findings include: 1. The laboratory does not have a Quality Assurance Plan procedure at the time of survey. 2. Review of twenty seven (27) management and adverse events reported using the Patient Incident Form from 12/21/2021 to 05/13/2022, the laboratory had no documentation of corrective actions to rectify these (27) management and adverse events. 3. The Lab Director and staff concurred with these findings on 06/03/2022 @ 10:30.AM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manuals, quality controls, calibrations and discussion with the staff the laboratory failed to monitor and evaluate the overall analytical system and correct identified problems. Refer to. D5403.
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: Based on review of quality control , calibration records and laboratory's procedure manual and interview with the Laboratory Director and Laboratory Manager on 06/03/2022 @ 11:00 the laboratory failed to follow written Standard operating procedures for specimen rejection criteria, processing, referral, calibrations, and quality controls. Findings include: 1. Eight (8) management and adverse events reported using the Patient Incident Form was reviewed from 12/21/2021 to 05/02/2022. Three (3) specimens were mislabeled. Four (4) specimens were not performed because no test were selected on the requisition forms, when the specimens were sent out to a reference laboratory and one(1) specimen was lost in the laboratory. The laboratory had no documentation of the root cause leading to these adverse events to happen and what measures were taken to rectify the problem. 2. Review of quality control (QC) results for the chemistry analyzer revealed 47/66 days that the QC were not within the laboratory's acceptable range for two to five analytes each day. Each day of patient testing performed no repeat quality control testing or documentation of corrective actions taken prior to release of patients results. 3. Three (3) out of three (3) days Occult blood testing quality controls were not perform. No documentation of corrective actions were taken prior to release of patients results. 4. Review of calibration records for the Sysmex XN1000 hematology analyzer showed calibrations were done on 05/19/2021 and 04/28/2022. Laboratory's standard operating procedure states calibration is done every six months. 5. The laboratory failed to follow the laboratory's SOP for performing six months calibrations on the XN1000 hematology analyzer. 6. The Lab Director and the staff concurred with these findings 06/03/2022 @ 11:00 AM.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of Personnel Records, Proficiency Testing records, Quality Control and calibration records, and Patients Incident and Safety Alert Forms, the Laboratory Director (LD) did not fulfill his responsibilities to provide overall management and direction of the laboratory. Refer to D6100 ,D6101, D6102, D6103.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Based on review of personnel records, CMS 209 form Laboratory personnel and interview with the Laboratory Director, Laboratory Manager, and hospital CEO on 06/03/2022 @ 09:00 AM the laboratory did not have a designated qualified general supervisor. Findings include: 1. Review of personnel records showed there was no qualified general supervisor to provide day to day on-site supervision of testing

	personnel performing high complexity testing at the time of survey. 2. The LD and staff concurred with this finding. on 06/03/2022 @ 09:00.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of personnel records, CMS 209 form Laboratory Personnel and interview with the Laboratory Director, Laboratory Manager on 06/03/2022 @ 09: 00AM the laboratory director failed to ensure that the laboratory had adequate testing personnel for the type and complexity of testing performed. Findings include: 1. The laboratory did not have a qualified General Supervisor (GS) at the time of survey. 2. The laboratory did not have a qualified Technical Supervisor (TS) at the time of survey. 3. The laboratory is open 24/7 and there are 3 of 4 traveling temporary testing personnel performing high complexity testing and one (1) traveling temporary testing personnel performing moderate complexity testing. 4. The LD and staff concurred with these findings 06/03/2022 @ 09:00.
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 personnel training records and discussion with the staff the laboratory failed ensure that testing personnel were trained to perform testing in all specialties and sub specialties of the laboratory prior to patient testing.. Findings include. 1. Five (5) out of five (5) testing personnel listed on the CMS form 209 do not have documentation of initial training to make sure each individual is trained and capable of running and troubleshooting the different instrumentations in the laboratory and have demonstrated each one of them can perform the test accurately and reliably. 2. Three (3) of three (3) testing personnel performing transfusion compatibility testing and the release of packed red blood cells, did not have documentation of training for transfusion services. 3. The LD and the staff concurred with these findings on 06/03 /2022 @ 09:00.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

	process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel and competency records and discussion with the staff the laboratory failed ensure that testing personnel were competent to perform testing in all specialties and sub specialties of the laboratory prior to patient testing.. Findings include. 1. Five (5) out of five (5) testing personnel do not have documentation of competency assessment to make sure each individual is competent and proficient to perform the test accurately and reliably. 2. Three (3) out of three (3) testing personnel performing transfusion compatibility testing and the release of packed red blood cells, did not have documentation of competency for transfusion services 3. The LD and the staff concurred with these findings on 06/03/2022 @ 09:00.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records, the laboratory's policy and procedures, training and competency records, quality control and calibration records, the Technical Supervisor (TS) did not fulfill his responsibilities to provide technical supervision of the laboratory. Refer to D6117, D6118, D6119 and D6120.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review or quality control records and discussion with the staff the technical supervisor failed to ensure that quality controls in chemistry and bacteriology where acceptable prior to releasing patient reports. Findings include: 1. Forty seven (47) out of sixty six (66) days Chemistry quality controls (QC) were not within the laboratory's acceptable parameters. Quality controls were not repeated to make sure QC were with acceptable parameters before testing and releasing patients results. 2. Three (3) out of three (3) days Occult blood testing quality controls were not perform. Quality controls must be perform before testing and releasing patients results. 3. The Lab Director and the staff concurred with these findings 06/03/2022 @ 09:30.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5)

	The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of quality control records and calibration records the technical supervisor failed to ensure that test procedures and verification processes were perform to establish accuracy and precision of the test system, and remedial actions were taken when laboratory deviates from this performance specifications. Findings include: 1. Forty seven (47) out of sixty six (66) days Chemistry quality controls were not within the laboratory's acceptable parameters. Refer to D5403 . 2. Three (3) out of three (3) days Occult blood testing quality controls were not perform. Refer to D5403 3. Calibrations for the Sysmex XN1000 per laboratory's standard operating procedure is every six months. Calibrations were performed 05/19/2021 and 04/28 /2022. Calibration procedure not followed. Refer to D5403 4. The Lab Director and the staff concurred with these findings 06/03/2022 @ 09:30.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on review of quality control records and patients result the technical supervisor failed to ensure that patients results were not reported until all corrective action have been taken and the test system is functioning properly. Findings include: 1. Quality control for hemoglobin A1C on 02/01/2022 was high. No repeat testing of QC performed. Patient results of 9.2 was resulted. 2. Quality control for troponin and TSH level 2 were high on 03/03/2022. No repeat testing of QC. Nine (9) TSH patient's results and four (4) troponin patient's results were reported. 3. The Lab Director and staff concurred with these findings on 06/03/2022 @ 10:00 AM.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of training and competency records and discussion with the staff the Technical Supervisor (TS) failed to assess and document competency testing of the testing personnels. Findings include. 1. Five (5) out of five (5) Testing Personnel(TP) do not have documentation of their initial training and competency evaluations. See

	D6102 and D6103. 2. Three (3) out of (3) testing personnel performing high complexity testing do not have documentation of initial training and competency assessment prior to release of patient's results. See D6102 and D6103. 3. The Lab Director and staff concurred with these findings 06/03/2022 @ 10:15.