Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2032859	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rehabilitative Health Services Medical Clinic	1675 Curlew Dr, Ammon, ID	

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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on a random review of patient records and an interview with testing personnel 1 (TP1) on 1/26/2021, the laboratory failed to retain or be able to retrieve a copy of the original test report for a patient for at least two (2) years after the date of reporting. The findings include: 1. A random review of patient records revealed that the laboratory was unable to retrieve patient AB's complete blood count (CBC) results from 10/13/2020. They were unable to retrieve the instrument printout and the results had not been uploaded into the patient chart. 2. An interview with testing personnel 1 (TP1) on 1/26/2021 at 2:30 pm confirmed that the laboratory was unable to obtain CBC results for patient AB performed on 10/13/2020. 3. The laboratory reports performing 2955 CBC tests annually.
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 training and competency records, the Centers for Medicare and

	Medicaid Services (CMS) 209 personnel form, and interview with laboratory testing personnel 1 (TP1) on 1/26/21, the laboratory failed to establish and follow written policies and procedures for initial training and assessment of new employees. The findings includes: 1. The laboratory's CMS-209 form identifies one (1) of four (4) testing personnel performing moderate complexity testing is new and did not have initial training documented for complete blood count (CBC) testing. 2. The laboratory did not establish policies or procedures for initial training and assessment of new employees. 3. An interview with testing personnel 1 (TP1) on 1/26/21 at 1:00 pm confirmed that the laboratory did not have initial training documentation for the one new testing personnel and did not have an established policy and procedure for initial training and assessment of new employees. 4. The laboratory reports performing 2955 CBC tests annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quaility Control (QC) records for the pocH-100i and an interview with the testing personnel 1 (TP1) on 1/26/2021 the laboratory failed to monitor over time the accuracy and precision of test performance of the pocH-100i that may be affected by changes in test system performance and environmental conditions, and variance in operator performance. The findings include: 1. The QC records for the pocH-100i revealed that the laboratory failed to monitor the QC of complete blood counts (CBC) over time to look for trends or shifts that may affect patient results. 2. The testing personnel confirmed by interview on 1/26/2021 at 1:29 pm that they monitor QC daily for CBC tests but that they do not monitor the QC over time for trends or shifts. 3. The laboratory reports performing 2955 CBC tests annually.