Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2162276	11/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ridgeline Medical	2470 Jafer Ct, Idaho Falls, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on interview with the laboratory director on 11/3/2020, and record review of the Centers for Medicare and Medicaid Services (CMS) CASPER 96D report, the laboratory failed to enroll in an Health and Human Services (HHS) approved proficiency testing (PT) program that meets the criteria in 42 C.F.R. part 493 subpart I for each of the specialties and subspecialties in Hematology, Chemistry, and Endocrinology for which it seeks certification. In accordance with 42 C.F.R. part 493. 1236(c)(1), for those tests not included in subpart I, the laboratory failed to, (at least twice annually) verify the accuracy of any test or procedure it performs. The findings include: 1. The laboratory performs complete blood counts (CBC) on a PocH 100i Hematology analyzer, and Free Thyroxine (FT4), Thyroid-stimulating hormone (TSH), Vitamin D, Prostate-specific antigen (PSA), and Testosterone on a NanoEnTek FREND System. 2. The NanoEnTek FREND System and the PocH 100i are classified by the Food and Drug Administration (FDA) as moderate complexity testing platform. The CBC analytes and the FT4, TSH are regulated analytes listed in 42 C.F.R. part 493 subpart I requiring PT enrollment with an HHS approved PT program. 3. In accordance with 42 C.F.R. part 493 subpart I, the laboratory failed to enroll in an HHS approved PT program for the regulated analytes FT4, TSH, and

	White Blood Cell differential counts (WBC), Erythrocyte (RBC) counts, Hemoglobin, Hematocrit and Platelets counts. 4. The laboratory failed to perform twice annual verification for accuracy or to enroll in an HHS approved PT program for the four non-regulated analytes FT4, TSH, Vitamin D, and Testosterone. 5. The laboratory has been open and testing patients analytes since January 2020. 6. The laboratory director confirmed by interview on 11/3/2020 at 9:10 a.m., that the laboratory did not enroll in an HHS approved PT program for the regulated analytes in accordance with 42 C.F.R. part 493.801 subpart I, and the laboratory did not perform verification of accuracy twice annually for the unregulated analytes that are not listed within 42 C.F.R. part 493 subpart I. 6. The laboratory records indicate that the laboratory performs 30,950 moderate complexity patient specimens annually.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the laboratory director (LD) and the office manager (OM) on 11/3/2020, the laboratory failed to retain quality control and patient test records (including instrument printouts) for at least 2 years. The findings included: 1. The laboratory performs complete blood counts on the PocH 110i hematology analyzer. During interview with the LD and the OM regarding QC records during a random review of patients records from January 1, 2020 through October 31, 2020, the laboratory did not have QC records from January 2020 through July 6, 2020. 2. The OM stated by interview on 11/3/2020 that the hematology analyzer QC records were misfiled in the transition from the original facility location to this facility location and the records prior to July were not available. 3. The laboratory does not have an integrated laboratory information system (LIS) and enters the patients laboratory results into the electronic health record (EHR) manually. The LD stated that patient analyzer test printouts are not saved, but shredded once the results are manually entered into the laboratory's EHR. 4. The laboratory director and office manager confirmed by interview on 11/3/2020 at 11:40 a.m. that the laboratory does not retain for two years patient printouts from the hematology analyzer, and that the laboratory did not have QC records from January 2020 through June 2020 available at the time of survey. 5. The laboratory reports performing 6000 CBC patient specimens 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 the laboratory's office manager (OM) on 11/03/20, the laboratory failed to establish and follow written

	policies and procedures to assess employee and, if applicable, consultant competency. The findings includes: 1. The laboratory's CMS-209 form identifies six (6) testing personnel performing moderate and waived complexity testing procedures. Four (4) of the (6) identified testing personnel did not have documentation of initial training and competency. Personnel Start Dates (1) MA 05-25-2020 (2) MA 08-26-2020 (3) MA 10-01-2020 (4) MA no training start date 2. For two (2) of six (6) testing personnel listed on the CMS-209, the laboratory did not have adequate documentation of competency which included the six parameters as listed in 493.1413(b)(8) for biannual and annual competency requirements and did not establish policies or procedures to monitor each testing individual for competency. 3. The laboratory has one technical consultant (TC) listed on the CMS-209, the laboratory had no documentation of competency for this individual. 4. The laboratory director and office manager confirmed by interview on 11/3/2020 that the laboratory does not have policies and procedures for initial training and competency assessments, biannual and annual competency assessment, in accordance with 42 C.F.R. 493.1413(b)(8). 5. The laboratory reports performing 1040 waived and 6,250 non-waived patient specimens 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 record review and interview with the laboratory director on 11/3/2020 , the laboratory failed to 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. The findings include: 1. The laboratory has no written policies or procedures for an ongoing mechanism to monitor, asses and when indicated identify general laboraory systems requiremenst such as training and competency assessments; See D5209, 2. The laboratory has no written policies or procedures for monitoring of maintanance and quality control performance; See D5421, D5403. 3. The laboratory does not have policies or procedures to ensure that patient testing records and printouts are maintained for two (2) years. See D3031.
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 the laboratory's policy and procedures, the laboratory's quality control (QC) records and interview with the laboratory director on 11/3/2020, the laboratory failed to ensure policies and procedures were established which included the following when applicable to the test procedure: (1) Requirements criteria for specimen acceptability and rejection as described in 493.1242. (5) Calibration and calibration verification procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (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. The findings include: 1. The laboratory performs moderate complexity testing on two analyzers the Sysmex Pochi (Hematology) and the FREND (endocrinology). The laboratory did not have policies or procedures for performing calibration and verifications procedures for when the analyzers are moved from one testing location to a new testing location. a. The laboratory had documentation of initial installation of the PocH 100i hematology and NanoEnTek FREND analyzers in January 2020. The laboratory moved to a new testing location on July 6, 2020 and initiated patient testing on July 14,, 2020. The laboratory did not have documentation of complete verification for the PocH 100i hematology analyzer and no documentation for the NanoEnTek FREND analyzer. b. The laboratory did not have procedures how or when to perform calibration and verification processes are to be performed and documented. 2. During a random review of patient test days from July 14, 2020 through October 31, 2020, the laboratory's QC records for the PocH 110i hematology analyzer revealed that the laboratory QC level (1) fell outside the laboratory's established ranges for acceptability three times; the QC records indicated those QC level samples were reran. There was no documentation of who performed the testing, and no documentation of corrective actions taken and if the corrective actions were successful. Date QC Level Patients tested 08/18/2020 Level 1 11 10/12/2020 Level 1 1 10/13/2020 Level 1 9 a. By interview on 11/3/2020 office manager (OM) verbalized a process the laboratory testing personnel are to take when QC does not fall within the laboratory's established ranges. The testing personnel are to initial and date the acceptable QC printout and place both into the QC log. b. Upon review of the QC records from July 2020 through October 2020, of three incidences in which the QC levels did not meet the laboratory's established ranges, only one had initials and date on it. c. The laboratory did not have corrective action policies or procedures of how or when the testing personnel are to document corrective actions; or who is responsible for reviewing and monitor of documentation of corrective actions. 3. The laboratory manually enters the patient test results for waived and non-waived tests into the patients electronic health record (EHR). a. The laboratory does not have a policy or procedure regarding entering results into the EHR, and what to do if or when the EHR becomes inoperable. 4. The laboratory director confirmed by interview that the laboratory does not have a policy or procedure for the above listed requirements for

	the procedure manual. 5. The laboratory reports performing 7,290 waived and non-waived patient specimens annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records and interview with the technical consultant on 11/3/2020, the laboratory failed to: (A) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy, (B) Precision, (C) Reportable range of test results for the test system. (B)Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings include: 1. The laboratory initiated testing in January 2020, and performed a verification for the Sysmex point of care Hematology (pocH-100i) analyzer. The laboratory then moved to a new testing location on July 6, 2020. 2 The laboratory failed to perform a complete verification of the PocH 100i hematology analyzer that included: precision studies, linearity or approval of the verification document by the laboratory director after the PocH 100i analyzer was installed at the new location prior to testing patient specimens. 3. The laboratory performs free Thyroxine (FT4), Thyroid-stimulating hormone (TSH), Vitamin D, testosterone and Pancreatic-specific antigen testing on the FREND platform. The laboratory did not have documentation of verification of testing prior to testing patient specimens after moving to the new testing location. 4. The laboratory office manager confirmed by interview on 11/3/2020 that the laboratory did not have a complete verification study performed for the PocH 100i analyzer and no documentation of the FREND analyzer prior to testing patient samples. 5. The laboratory reports performing 6000 Hematology patient specimens, and 950 Chemistry patient specimens annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the systemic nature of the deficiencies identified at the time of survey and interviews with the laboratory director and the office manager on 11/3/2020, the laboratory director failed to provide overall management and direction in accordance with 493.1407. The findings included: 1. The laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program prior to performing patient testing. See D2000, D6015. 2. The laboratory director failed

	ensure that policy's and procedures were established to ensure testing personnel trained and competent and maintained their competency prior to performing patient testing. See D5209, D6030. 3. The Laboratory director failed to ensure policies and procedures were established for an ongoing mechanism to monitor , assess and when indicated correct problems identified in the general laboratory systems. See D5291, D6022.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director on 11/3/2020. the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing (PT) program for the testing performed. The findings include: 1. During the entrance interview with the laboratory director (LD) and the office manager on 11/3/2020, the laboratory LD stated that they had not enrolled in an HHS approved PT program and had not performed PT activities for the Hematology testing. See D2000 2. During the tour of the laboratory testing area, it was identified that the laboratory performs Free Thyroxine (FT4), Thyroid-stimulating hormone (TSH), Testosterone, vitamin D and Prostate-specific antigen (PSA) testing on the FREND analyzer (determined by the FDA as a moderate complexity methodology). See D2000 3. The laboratory had not enrolled in an HHS approved PT program for FT4, TSH. See D2000. 4. The laboratory and did not have documentation of twice annual verification of accuracy for the analytes not listed in 43 C.F.R. 493 Subpart I for PSA, Vitamin D and testosterone. See D2000
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on reveiw of the laboratory quality control (QC) records and interview with the technical consultant on 11/3/2020, the laboratory director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. The findings include: 1. The laboratory director failed to establish a quality assessment program to identify failures in QC and corrective actions. See D5793, D5403.

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 records and interview with the laboratory office manager on 11/3/2020, the laboratory director failed to 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. The findings include: 1. The laboratory failed to establish policies and procedures for initial, biannual, and annual training and competencies and to monitor and ensure that all testing personnel maintain thier competency. See D5209.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview with the office manager on 11/3/2020, the technical consultant failed to ensure verification of the test procedures were performed and established including the precision and accuracy of each test and test system. The findings include: 1. The laboratory consultant failed to ensure a complete verification process had been performed on the PocH-100i hematology analyzer and the FREND analyzer prior to testing patience specimens after the moving it from one testing location to a new testing location. See D5421.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by:

	Based on record review of the staff competency records and interview with the office manager on 11/3/2020, the Technical Consultant (TC) failed to ensure the procedures for evaluation of the competency of the staff included, (but are not limited to), direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. The findings include: 1. The office manager presented a check list for testing personnel with identifiers on the top for six month and annual competencies. 2. The check list did not identify if the competency was determined by direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing, or proficiency testing. 3. By interview with the with the office manager on 11/3/2020, the office manager could not identify which analyzers/instruments/tests the competency was applied to and which parameter's above were used to determine the staff competency. 4. Four (4) of the 6 testing personnel identified on the CMS-209 laboratory personnel form did not have initial training and competency assessments documented. 5. The laboratory performs 7,290 waived and non-waived patient tests annually.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must 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 the laboratory quality control (QC) records and maintenance logs for the pocH-100i, (on which complete blood counts (CBC) are ran), the individuals performing moderate complexity testing failed to document all quality control activities, instrument and procedural calibrations, and maintenance performed. The findings include: 1. Review of the laboratory's maintenance logs, the bi-weekly maintenance for the PocH 100i analyzer was not documented as performed for the months of April and July 2020; and the maintenance logs were not reviewed and signed for the months of February, April, and July of 2020. 2. During the interview the office manager stated that QC failures were to be noted on the QC printout by the testing personnel running the QC, along with their initials and date. For three (3) of four (4) dates reviewed in which QC failure occurred, the testing personnel did not initial and date the QC printout. 3. For the date 10/28/2020, the laboratory had no documentation of QC level one being ran on the pocH-100i and 2 patients were recorded as tested that day. 4. The office manager confirmed by interview on 11/3 /2020 at 10:45 a.m., that the laboratory testing personnel are not documenting maintenance performed as established by the laboratory, and do not document QC failures with corrected actions per verbal instructions. 5. The laboratory reports performing 6000 patient CBC specimens annually.