Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0915829	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medhelp 280	4600 Highway 280 E, Birmingham, AL	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the General Supervisor (Testing Personnel #1), the surveyor determined the laboratory failed to self-evaluate (grade) proficiency testing scores returned ungraded from API. This affected Event #1, 2019 and Event #1, 2018, two of seven testing events reviewed by the surveyor. The findings include: 1. A review of API proficiency testing records revealed the following: a) The KOH (Potassium Hydroxide Preparation) and the Urine Sediment Examination were not graded by API on Hematology, Event #1, 2019. The laboratory did not document a review and evaluation of the results to determine the laboratory's accuracy of interpretation. The staff documented no action was taken. b) For Event #1, 2018, specimen CHO2 for Cholesterol (Chemistry) was not graded by API. The result report included a question mark (?) next to the value, however no documentation was provided of a review and evaluation to determine the laboratory's accuracy of testing. 2. In an interview at 2:19 PM on May 22, 2019, the surveyor inquired of what action was taken for ungraded proficiency testing results. Testing Personnel (TP) #1 stated she was not sure what "no consensus" meant. The surveyor discussed the laboratory's responsibility to evaluate scores returned from the proficiency testing provider as not graded. TP #1 confirmed the above noted findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2017-2019 American Proficiency Institute (API) proficiency testing records, and an interview with the General Supervisor [Testing Personnel (TP) #1, the only personnel interpreting the microscopics and Chemistry testing], the surveyor determined the laboratory failed to implement and document corrective actions for the interpretations of Vaginal Wet Preparations (non-regulated analyte, which the laboratory was enrolled in organized proficiency testing), after repeated failures. The laboratory further failed to ensure corrective actions were taken for a Free T4 (Free Thyroxine) score of less than one hundred percent (%). This affected four of seven testing events reviewed by the surveyor. This is a repeat deficiency. The findings include: 1. A review of the API proficiency testing records revealed the following laboratory scores: a) Zero percent for the Vaginal Wet Preparation (VA 01) on Event #1, 2017. The staff who performed the test (TP #1) documented she educated herself on clue cells. b) Zero percent for the Vaginal Wet Preparation (VA 03) on Event #3, 2018. The staff who performed the test (TP #1) documented she was having a hard time distinguishing clue cells in the photos. c) Zero percent for the Vaginal Wet Preparation (VA 02) on Event #2, 2018. Staff documented she was having trouble distinguishing. d) The laboratory scored 80 % for the Free T4 for Event #2, 2018, but did not implement and document corrective actions for the less than one hundred percent score. 2. In an interview on May 22, 2019 at 2:19 PM, TP #1 confirmed the above noted scores. TP #1 stated she reviewed the pictures after the failure on Event #1, 2017 of the Vaginal Wet Preparation. The surveyor discussed with TP #1 the need to possibly review additional photos containing elements which may be found in vaginal wet preparations. 3. Please refer to D6054, the failure to assess the testing skills (the competency) of TP #1, who serves as the General Supervisor of the laboratory, and who is responsible for at least four additional laboratories.
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 initial tour observations, a review of the installation records for the Horiba ABX Micros 60 [one for Main Lab and one for Sub Lab (Urgent Care)], and the Tosoh G8, and interviews with the General Supervisor (also Testing Personnel #1), the surveyor determined the laboratory failed to ensure all performance specifications were verified for the Horiba Micros 60, prior to patient testing. The laboratory further failed to ensure the raw data generated for the performance specifications verifications (accuracy, precision and reportable range studies) was reviewed, evaluated and

	approved by the Laboratory Director, prior to allowing the instruments to be used for patient testing. This affected three of three newly installed instruments, since the previous survey in March of 2017. The findings include: A. 1. During the initial tour of the laboratory on May 22, 2019 at 10:00 AM, the General Supervisor reviewed the test menu with the surveyor and indicated the Tosoh G8 for Hemoglobin A1C testing was new, as well as the Horiba ABX Micros 60 for Hematology testing [Complete Blood Counts (CBCs)]. 2. A review of the installation records for the Horiba ABX Micros 60 (SN 707CS96830), for the Sub Lab, revealed the instrument was installed and calibrated on 12/05/2017. The linearity worksheets had not been completed. Although the precision and accuracy had been performed, none of the data generated to verify the manufacturer's claims of precision, accuracy or reportable ranges had been reviewed and evaluated, nor signed by the Laboratory Director. 3. A review of the "RBC/HGB/HCT Linearity Worksheet" by R&D SYSTEMS and Bio-techne brand revealed the following instructions: "Instructions to obtain a computerized data analysis: Purchase of a CBC-LINE kit entitles you to a single, computer analysis of your linearity data. However, you MUST send the worksheet for analysis with the original Certificate Label... 1. Record the individual results from all four runs on Line #1... 2. Record evaluation limits on Line #6. Evaluation limits may be obtained from instrument manufacturer or established within your own laboratory. 3. Photocopy the completed form for your records. Send the completed worksheet to Verified Medical Research, Inc., ..." 4. A review of the package insert for CBC-LINE (Full/Low Range Hematology Linearity Kit) by R&D SYSTEMS revealed the following: "SUMMARY AND PRINCIPLE CAP requirements and CLIA regulations both mandate that laboratories establish reportable range for each test method. It is good laboratory practice to verify reportable range at initial set up of analyzer, following significant preventative maintenance, unusual trend or shift in controls and as recommended by the instrument manufacturer." Instructions under the section, Analyze CBC-LINE, included instructions to complete the worksheet and evaluate the results. Further instructions included: "...Each lab must define its own acceptable limits that can be used by the laboratory director to establish acceptable analytical performance criteria and a reportable range to ensure test results are consistent with the medical needs of the patient." 5. The above noted deficient practice was confirmed by the General Supervisor [Testing Personnel (TP #1)] at 3:30 PM on May 22, 2019. At 5:32 PM, the General Supervisor stated patient testing started, at the earliest, a day after each new instrument was installed. B. 1. A review of the installation records for the Horiba ABX Micros 60 (SN 706CS96925), for the Main Lab, revealed the instrument was installed and calibrated in November of 2017. The data for the reportable range study had been hand-written on linearity worksheets, but had not been evaluated. Although the precision and accuracy studies had been performed, none of the data generated to verify the manufacturer's claims of precision, accuracy or reportable ranges had been reviewed and evaluated, nor signed by the Laboratory Director. 2. The above noted deficient practice was confirmed by the General Supervisor (TP #1) at 3:30 PM on May 22, 2019. C. 1. On May 22, 2019 at 4:00 PM, a plastic sleeve, labeled Method Validation, was presented for the Tosoh G8. The contents included instrument tapes (printouts) of a calibration and quality control, precision and carryover, and linearity, dated 6/11/18. There was no evidence the Laboratory Director had reviewed and evaluated the data to ensure the accuracy of the studies, nor had the Laboratory Director signed the studies, which would be accepted as approval by the director for the instrument to be used by the testing personnel to analyze patient specimens. 2. At 5:51 PM on May 22, 2019, the General Supervisor confirmed the above noted findings, and stated patient testing on the Tosoh began on June 13, 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on calibration verification records for the Vitros 350 and Architect Plus, a review of the policy and procedure manual, and an interview with the General Supervisor (Testing Personnel #1, the only employee who performs the Chemistry /Endocrinology testing), the surveyor determined the laboratory failed to perform calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This affected one opportunity of two for 2017, to perform the calibration verification for PSA (Prostate Specific Antigen), Free T3(Free Triiodothyronine) and TSH (Thyroid-Stimulating Hormone) analyzed on the Architect. Additionally, the laboratory had not performed a calibration verification in 2019 (due March 2019). This deficient practice also affected Sodium (Na), Potassium (K), and Chloride (Cl), performed on the Vitros 350. The calibration verifications for Na, K, and Cl have not been performed, since October 1, 2018. The laboratory further failed to have established and accessible polices and procedures for calibration verifications. The findings include: 1. A review of the calibration verification records for the Architect Plus revealed, the verifications had been performed for Free T3, TSH and PSA on 4/28/17, 3/26/18 and 9/20/18. The calibration verification that should have been performed in October of 2017 was missed. Additionally, there had not been a calibration verification performed on these analytes since September of 2018, exceeding the every six months requirement. 2. A review of the records for the Vitros 350 revealed the Na, K and Cl calibration verifications had been performed In April and September of 2017 and March and October of 2018, but none since October 1, 2018, exceeding the every six months requirement. 3. A review of the MedHelp 280 Policies and Procedures Manual revealed a statement and list of approved user's manuals, signed by the laboratory director on 1/01/14 and revised 11/8/18. The list of approved users' manuals indicated the Triage Meter, Horiba Micros 60, Clinitek Status, and Alere Affinion. The Vitros 350 and the Architect Plus were not included on this list; nor did the manual include other policies and procedures which may indicate specifics of calibration verification requirements. At 5:32 PM on May 22, 2019, the General Supervisor (GS) stated other than what might be in the operators'

	manuals, MedHelp 280 did not have any established protocols for calibration verifications. 4. In an interview on May 22, 2019 at 6:35 PM, the surveyor again inquired about the polices for calibration verification performance. The GS, the only testing personnel who utilizes the two Chemistry analyzers, stated the manual for the Architect was online. The GS further stated that although she searched on-line with the analyzer to locate the procedure, no procedure could be accessed. Several minutes later, the GS stated she called the manufacturer, who informed her Free T3, TSH, and PSA required calibration verifications at least every six months, because the analytes only have two routine calibrators. The GS reviewed the records for the Architect Plus and confirmed the calibration verification had been missed in October of 2017. The performance of the calibration verification in 2019 had not been performed and was late, due to the representative ruining the reagents when on-site performing other maintenance. The laboratory was in the process of replacing the reagents. 5. At 7:17 PM on May 22, 2019, the GS stated all analytes on the Vitros were routinely calibrated with at least three calibrators, and she was told to routinely calibrate every six months, but does the calibrations more often. At this time, the surveyor discussed the difference in routine calibrations and calibration verifications, as well as the CLIA requirement for calibration verifications. The surveyor stated to the GS to confirm the laboratory's practices with the manufacturer's guidelines. It is important to note the GS's competency as testing personnel had not been assessed by the Technical Consultant nor the Laboratory Director for the last two years. The GS (Testing Personnel #1) is the only Chemistry technologist for the laboratory, and her responsibilities include at least four other laboratories. Please refer to D6054. 6. The surveyor received a telephone call, voice-mail message from the GS on 5/28/2019 at 2: 57 PM. The GS stated Sodium, Potassium and Chloride were routinely calibrated with a two-point calibration. Thus, a six month calibration verification is needed for these analytes.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records for Chemistry testing and an interview with the General Supervisor [Testing Personnel #1, the only Chemistry technologist], the surveyor determined the laboratory failed to provide documentation of at least two acceptable levels of Quality Control (QC) for SHBG (Sex Hormone Binding Globulin) for at least eleven days in April of 2019. The laboratory did not provide documentation of at least two levels of acceptable QC, prior to patient testing and reporting of laboratory results on these days. This is a repeat deficiency. The findings include: 1. A review of the quality control records for Chemistry and Endocrinology testing, performed on the Architect Plus, for SHBG, revealed several days (between April 1-12, April 23 and 30, 2019) when documentation indicated that not at least two levels of QC were within acceptable ranges: a) The monthly instrument printout for SHBG indicated Level 3 of two levels tested was outside of acceptable limits on April 1, 2, 3, 4, 5, 8, 9, 10, and 11. Additionally, Level 1 was outside of acceptable limits on April 2, 23 and 30. 2. At 5:50 PM on May 22, 2019, the surveyor and testing personnel reviewed the Chemistry QC reports for April 2019. TP #1 explained the QC values must have shifted when the ranges were changed. TP #1 could not provide

	documentation of the quality control, prior to the ranges being changed. Therefore, no documentation could be provided the laboratory had at least two levels of acceptable QC, prior to testing patient specimens and reporting the results. 3. During the exit interview on May 22, 2019 at 7:17 PM, the surveyor gave the testing personnel additional time (until Tuesday, May 28) to provide documentation of acceptable quality control and the number of patients tested. No further information was received by the State Agency at the time of this report, June 7, 2019 at 9:30 AM.
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 review of quality control records for Chemistry testing, a review of calibration records for Hematology (two Horiba Micros 60 instruments), and interviews with the General Supervisor [Testing Personnel (TP) #1], the surveyor determined: 1. The laboratory failed to ensure a mechanism was implemented to ensure quality control reports were maintained to represent accurate quality control limits and acceptability, following times when ranges required adjustments. The laboratory staff printed quality control records, following range adjustments, unknowing the system shifted the translation of the data in the file based on the adjustments made. This affected quality control for SHBG (Sex Hormone Binding Globulin) for at least eleven days in April of 2019. 2. The laboratory failed to ensure calibration material was available for calibration performance at the usual six-month intervals. The laboratory failed to ensure a written procedure of calibration for the Horiba Micros 60, Hematology analyzers was included in the policy and procedure manual provided for review. The findings include: 1. Refer to D5481. 2. A review of the calibration records for the Horiba Micros 60 for the Sub Lab (Urgent Care) revealed the instrument was calibrated on 7/13/18 and not again until 3/07/19, eight months later. A review of the calibration records for the Hematology analyzer for the Main Lab revealed the instrument was calibrated on 7/30/18 and not again until 3/05 /19, about eight months after the previous calibration. At 5:32 PM on May 22, 2019, the surveyor inquired of the laboratory's policy and procedure for calibrations on the Horiba. TP #1 stated the only policy and procedure would be found in the manufacturer's operators' manual. The frequency of calibration was not clarified by a policy, operator's manual nor an established laboratory policy and procedure. However, the history indicated the laboratory had been calibrating every six months, except for the above mentioned timeframes. In an interview on May 22, 2019 at 6:50 PM, TP #1 (the laboratory's General Supervisor) stated she did not realize the manufacturer had not sent the calibrators, until after the calibration due-date. Further explanation revealed the calibrators had been sent to a different laboratory; and when the location of the calibrators were realized, the calibrators had expired and were re-ordered.
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 initial tour observations, a review of installation and validation records, a review of calibration records, a review of personnel records, a review of the policy and procedure manual and lack of documentation, and interviews with the General Supervisor (also Testing Personnel #1), the surveyor determined the Laboratory Director failed to fulfil his responsibilities as follows: 1. To ensure all performance specifications were verified for the Horiba Micros 60, prior to patient testing. The Laboratory Director further failed to review, evaluate and approve the installation and performance specifications of each of the new instruments, prior to allowing the instruments to be used for patient testing. This affected three of three newly installed instruments, since the previous survey in March of 2017. 2. To ensure performance of analytical measurement of reportable ranges were verified and maintained to assure instruments maintained acceptable levels of accuracy. To ensure laboratory staff performed calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This affected one opportunity of two for 2017, to perform the calibration verification for PSA (Prostate Specific Antigen), Free T3(Free Triiodothyronine) and TSH (Thyroid-Stimulating Hormone) analyzed on the Architect. Additionally, the laboratory had not performed a calibration verification in 2019 (due March 2019). This deficient practice also affected Sodium (Na), Potassium (K), and Chloride (Cl), performed on the Vitros 350. The calibration verifications for Na, K, and Cl have not been performed, since October 1, 2018. The laboratory further failed to have established and accessible polices and procedures for calibration verifications. 3. To ensure the competency, the testing skills, of TP #1, was assessed at least annually, and had demonstrated reliable test performance. This affected the survey review period, March 2017 until current survey on May 22, 2019, and the only testing personnel at the laboratory who performs Chemistry testing. This testing personnel also served as General Supervisor to this laboratory, as well as four other laboratories. 4. To ensure the testing personnel was provided policies and procedures for performance of calibration verifications for the Architect Plus and the Vitros 350. The laboratory failed to have established and accessible polices and procedures for calibration verifications, as described in D5439 and D6023. The findings include: 1. Refer to D6013. 2. Refer to D6023. 3. Refer to D6029. 4. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on initial tour observations, a review of the installation records for the Horiba ABX Micros 60 [one for Main Lab and one for Sub Lab (Urgent Care)], and the

Tosoh G8, and interviews with the General Supervisor (also Testing Personnel #1), the surveyor determined the Laboratory Director failed to fulfil his responsibilities to ensure all performance specifications were verified for the Horiba Micros 60, prior to patient testing. The Laboratory Director further failed to review, evaluate and approve the installation and performance specifications of each of the new instruments, prior to allowing the instruments to be used for patient testing. This affected three of three newly installed instruments, since the previous survey in March of 2017. The findings include: A. 1. During the initial tour of the laboratory on May 22, 2019 at 10:00 AM, the General Supervisor reviewed the test menu with the surveyor and indicated the Tosoh G8 for Hemoglobin A1C testing was new, as well as the Horiba ABX Micros 60 for Hematology testing [Complete Blood Counts (CBCs)]. 2. A review of the installation records for the Horiba ABX Micros 60 (SN 707CS96830), for the Sub Lab, revealed the instrument was installed and calibrated on 12/05/2017. The linearity worksheets had not been completed. Although the precision and accuracy had been performed, none of the data generated to verify the manufacturer's claims of precision, accuracy or reportable ranges had been reviewed and evaluated, nor signed by the Laboratory Director. 3. A review of the "RBC/HGB/HCT Linearity Worksheet" by R&D SYSTEMS and Bio-techne brand revealed the following instructions: "Instructions to obtain a computerized data analysis: Purchase of a CBC-LINE kit entitles you to a single, computer analysis of your linearity data. However, you MUST send the worksheet for analysis with the original Certificate Label... 1. Record the individual results from all four runs on Line #1... 2. Record evaluation limits on Line #6. Evaluation limits may be obtained from instrument manufacturer or established within your own laboratory. 3. Photocopy the completed form for your records. Send the completed worksheet to Verified Medical Research, Inc., ..." 4. A review of the package insert for CBC-LINE (Full/Low Range Hematology Linearity Kit) by R&D SYSTEMS revealed the following: "SUMMARY AND PRINCIPLE CAP requirements and CLIA regulations both mandate that laboratories establish reportable range for each test method. It is good laboratory practice to verify reportable range at initial set up of analyzer, following significant preventative maintenance, unusual trend or shift in controls and as recommended by the instrument manufacturer." Instructions under the section, Analyze CBC-LINE, included instructions to complete the worksheet and evaluate the results. Further instructions included: "...Each lab must define its own acceptable limits that can be used by the laboratory director to establish acceptable analytical performance criteria and a reportable range to ensure test results are consistent with the medical needs of the patient." 5. The above noted deficient practice was confirmed by the General Supervisor [Testing Personnel (TP #1)] at 3:30 PM on May 22, 2019. At 5:32 PM, the General Supervisor stated patient testing started, at the earliest, a day after each new instrument was installed. B. 1. A review of the installation records for the Horiba ABX Micros 60 (SN 706CS96925), for the Main Lab, revealed the instrument was installed and calibrated in November of 2017. The data for the reportable range study had been hand-written on linearity worksheets, but had not been evaluated. Although the precision and accuracy studies had been performed, none of the data generated to verify the manufacturer's claims of precision, accuracy or reportable ranges had been reviewed and evaluated, nor signed by the Laboratory Director. 2. The above noted deficient practice was confirmed by the General Supervisor (TP #1) at 3:30 PM on May 22, 2019. C. 1. On May 22, 2019 at 4: 00 PM, a plastic sleeve, labeled Method Validation, was presented for the Tosoh G8. The contents included instrument tapes (printouts) of a calibration and quality control, precision and carryover, and linearity, dated 6/11/18. There was no evidence the Laboratory Director had reviewed and evaluated the data to ensure the accuracy of the studies, nor had the Laboratory Director signed the studies, which would be accepted as approval by the director for the instrument to be used by the testing personnel to

	analyze patient specimens. 2. At 5:51 PM on May 22, 2019, the General Supervisor confirmed the above noted findings, and stated patient testing on the Tosoh began on June 13, 2018.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on calibration verification records for the Vitros 350 and Architect Plus, a review of the policy and procedure manual, and an interview with the General Supervisor (Testing Personnel #1, the only employee who performs the Chemistry /Endocrinology testing), the surveyor determined the Laboratory Director failed to ensure performance of analytical measurement of reportable ranges were verified and maintained to assure instruments maintained acceptable levels of accuracy. The laboratory staff failed to perform calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This affected one opportunity of two for 2017, to perform the calibration verification for PSA (Prostate Specific Antigen), Free T3(Free Triiodothyronine) and TSH (Thyroid-Stimulating Hormone) analyzed on the Architect. Additionally, the laboratory has not performed a calibration verification in 2019 (due March 2019). This deficient practice also affected Sodium (Na), Potassium (K), and Chloride (Cl), performed on the Vitros 350. The calibration verifications for Na, K, and Cl have not been performed, since October 1, 2018. The laboratory further failed to have established and accessible polices and procedures for calibration verifications. The findings include: 1. Refer to D5439.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 observations made during the initial laboratory tour at 10:00 AM on May 22, 2019, a review of personnel records, and an interview with the General Supervisor [also Testing Personnel (TP) #1 (the only Chemistry testing personnel)], the surveyor determined the Laboratory Director failed to ensure the competency, the testing skills, of TP #1, was assessed at least annually. This affected the survey review period, March 2017 until current survey on May 22, 2019, and the only testing personnel at

	the laboratory who performs Chemistry testing. The findings include: 1. During the initial tour of the laboratory on 5/22/19, the General Supervisor stated the Vitros 350 and the Architect Plus were used to perform Chemistry testing, including Endocrinology testing. 2. A review of the personnel file for TP #1(General Supervisor) revealed assessments for 6/1/18 and 6/14/17, titled "General Supervisor Competency Evaluation." Both of these documents were signed by the Laboratory Director on 5/19/19. 2. A review of the "General Supervisor Competency Evaluation" listed the following areas of assessment: "Is accessible to testing personnel at all times testing is performed... Provides day to day supervision of personnel performing moderate complexity testing. Must be on-site to provide direct supervision when moderate complexity testing is performed... Monitors test analyses and specimen examination to ensure that acceptable levels of analytic performance are maintained. Fulfils certain responsibilities as delegated by the Lab Director and/or Technical Supervisor, which may include: Resolving technical problems and ensuring corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications; Ensuring patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; Providing orientation to all testing personnel; and Evaluating and documenting the performance of all testing personnel as required. Note: If the General Supervisor performs testing they are also required to undergo competency assessment as testing personnel." 3. In an interview on 5/22/19 at 2:00 PM, the surveyor asked TP #1 if assessments had been done of her testing skills. TP #1 (the General Supervisor) confirmed no competency assessments had been performed of her testing skills; although she had spoken with the Technical Consultant about the need to do so. TP #1 confirmed she was the only testing personnel to perform Chemistry testing on the Vitros and Architect, as well as the microscopic examinations, which included vaginal wet preparations (Parasitology and Mycology) and urine sediment examinations. During this interview, TP #1 stated she was responsible for five laboratories, including this location.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on calibration verification records for the Vitros 350 and Architect Plus, a review of the policy and procedure manual, and an interview with the General Supervisor (Testing Personnel #1, the only employee who performs the Chemistry /Endocrinology testing), the surveyor determined the Laboratory Director failed to ensure the testing personnel was provided policies and procedures for performance of calibration verifications for the Architect Plus and the Vitros 350. The laboratory failed to have established and accessible polices and procedures for calibration verifications, as described in D5439 and D6023. The laboratory staff failed to perform calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This affected one opportunity of two for 2017, to perform the calibration verification for PSA (Prostate Specific Antigen), Free T3(Free

	Triiodothyronine) and TSH (Thyroid-Stimulating Hormone) analyzed on the Architect. Additionally, the laboratory has not performed a calibration verification in 2019 (due March 2019). This deficient practice also affected Sodium (Na), Potassium (K), and Chloride (Cl), performed on the Vitros 350. The calibration verifications for Na, K, and Cl have not been performed, since October 1, 2018. The findings include: 1. Refer to D5439 and D6023.
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 initial tour observations, a review of the installation records for the Horiba ABX Micros 60 [one for Main Lab and one for Sub Lab (Urgent Care)], and the Tosoh G8, and interviews with the General Supervisor (also Testing Personnel #1), the surveyor determined the Technical Consultant failed to ensure the performance specifications were verified for the Horiba Micros 60, prior to patient testing. The Technical Consultant further failed to ensure the raw data accumulated, during the installation and validation processes of the new analyzers, were reviewed, evaluated and approved, prior to allowing the instruments to be used for patient testing. This affected three of three newly installed instruments, since the previous survey in March of 2017. The findings include: 1. Please refer to D5421 and D6013.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: Based on a review of the 2017-2019 American Proficiency Institute (API) proficiency testing records, and an interview with the General Supervisor [Testing Personnel (TP) #1, the only personnel interpreting the microscopics], the surveyor determined the Technical Consultant failed to identify the training needs of TP #1, after repeated failures to accurately interpret elements found in Vaginal Wet Preparations of proficiency testing photos. The laboratory failed three Vaginal Wet Preparations of the seven proficiency testing events reviewed by the surveyor. The findings include: 1. Please refer to D5221.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the General Supervisor [also Testing Personnel (TP) #1], the surveyor determined the Technical Consultant failed to assess the competency of TP #11, semiannually, during the employee's first year as testing personnel of moderate-complexity testing. This affected one of fourteen testing personnel. The findings include: 1. A review of the personnel file for TP #11 revealed the testing personnel was hired on 1/21/2018, and was initially trained on 1/30/2018 2. In an interview on 5/22/19 at 2:00 PM, the surveyor asked the General Supervisor about the hire date, initial training and missed competency assessments for TP #11. When asked about the competency assessments for TP #11, the General Supervisor stated the semiannual was missed, as well as the annual assessment. The General Supervisor believed the assessments might have been missed, because TP #11 worked on a part-time basis.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on observations made during the initial laboratory tour at 10:00 AM on May 22, 2019, a review of personnel records, and an interview with the General Supervisor [also Testing Personnel (TP) #1 (the only Chemistry testing personnel)], the surveyor determined the Technical Consultant failed to assess the competency, the testing skills, of TP #1, at least annually. This affected the survey review period, March 2017 until current survey on May 22, 2019, and the only testing personnel at the laboratory who performs Chemistry testing. The Technical Consultant further failed to assess the competency of TP #11, semiannually after the testing personnel was trained and started patient testing. Additionally, no annual competency assessment was done on TP #11, since her date-of-hire on 1/21/18. The findings include: 1. During the initial tour of the laboratory on 5/22/19, the General Supervisor stated the Vitros 350 and the Architect Plus were used to perform Chemistry testing, including Endocrinology testing. 2. A review of the personnel file for TP #1(General Supervisor) revealed assessments for 6/1/18 and 6/14/17, titled "General Supervisor Competency Evaluation." Both of these documents were signed by the Laboratory Director on 5/19 /19. 2. A review of the "General Supervisor Competency Evaluation" listed the following areas of assessment: "Is accessible to testing personnel at all times testing is performed... Provides day to day supervision of personnel performing moderate complexity testing. Must be on-site to provide direct supervision when moderate complexity testing is performed... Monitors test analyses and specimen examination to ensure that acceptable levels of analytic performance are maintained. Fulfils certain responsibilities as delegated by the Lab Director and/or Technical Supervisor, which may include: Resolving technical problems and ensuring corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications; Ensuring patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; Providing orientation to all testing personnel; and Evaluating and documenting the performance of all testing personnel as required. Note: If the General Supervisor performs testing they are also required to undergo competency assessment as testing personnel." 3. In an interview

	on 5/22/19 at 2:00 PM, the surveyor asked TP #1 if assessments had been done of her testing skills. TP #1 (the General Supervisor) confirmed no competency assessments had been performed of her testing skills; although she had spoken with the Technical Consultant about the need to do so. TP #1 confirmed she was the only testing personnel to perform Chemistry testing on the Vitros and Architect, as well as the microscopic examinations, which included vaginal wet preparations (Parasitology and Mycology) and urine sediment examinations. During this interview, TP #1 stated she was responsible for five laboratories, including this location. When asked about the competency assessments for TP #11, the General Supervisor stated the semiannual was missed, as well as the annual assessment.