Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2227283	02/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sollis Health Fl Inc	324 Royal Palm Way Suite 100, Palm Beach, FL	

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
D0000	An announced initial survey was conducted on 01/17/2023 to 02/10/2023 at Sollis Health FL Inc., a clinical laboratory in Palm Beach, Florida. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 10:15 PM on 02/07/2023. The following Conditions were not met: D5400- Analytic Systems 493.1250 D6000- Moderate Complexity Laboratory Director 493.1403
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 observation, review of manufacturers' instructions, temperature chars, Hematology analyzer calibration records, calibration records, and maintenance logs, quality control records, and Individual Quality Control Plan documents, and interview the Laboratory failed to store respiratory controls per the manufacturer's instruction and failed to record room temperature and humidity (See D5413), failed to perform calibration verification for the Hematology analyzer (See D5439), failed to perform maintenance on the Hematology analyzer (See D5429), failed to monitor over time Hematology quality control for shifts and trends (See D5441), failed to perform quality control per the manufacturer's requirements or the Laboratory's Individual

	Quality Control Plan (See D5445), failed to establish a Quality Assessment plan (See D5791), and failed to perform instrument comparisons for the 2 Film Array BioFire instruments (See D5775).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observations of the freezer, review of manufacturer's instructions, temperature logs, and interview, the laboratory 1. failed to store BioFire respiratory controls within manufacturer's instructions temperature ranges and 2. failed to record room temperature and humidity since testing began on 05/08/2022. Findings Included: 1. During a tour of the laboratory on 01/17/2023 at 10:00 AM a freezer was observed set at -30 degrees Celsius. Inside this freezer was BioFire PR2.1/RP2.1plus Control Panel (respiratory panel quality control lot# H14DEC21 expiration-03/31/2023). On the box it stated to store the contents at -15 to -25 degrees Celsius. Review of freezer temperatures recorded on the "Monthly Temperature Log" revealed from 06/01/2022 to 12/31/2022 the freezer was -30 degrees Celsius every day. In an interview on 01/17 /2023 at 10:30 AM, the Laboratory Manager confirmed that the freezer was set to -30 degrees Celsius and that it was colder than the minimum storage temperature for the respiratory panel quality controls. 2. Review of the "Monthly Temperature Log" revealed no room temperature or humidity recorded from 06/01/2022 to 12/31/22. The January 2023 log did not have room temperature or humidity recorded. Review of the manufacturers' instructions for the instruments in the laboratory revealed: 1) the Abaxis Piccolo Xpress ambient operating temperature was 15-32 degrees Celsius and 8-80% humidity, 2) the pocH 100i ambient operating temperature is 15-30 degrees Celsius and 30-80% humidity, 3) the Film Array BioFire ambient operating temperature is 15-30 degrees Celsius and 20-80% humidity, and 4) the Quidel Triage MeterPro ambient operating temperature was 15-30 degrees Celsius and 10-85% humidity. In an interview on 01/18/2023 at 12:30 PM, the Laboratory Manager confirmed that the room temperature and humidity were not documented.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of maintenance logs, and interview, the laboratory failed to perform maintenance on the pocH 100i Hematology analyzer for 11 (March 2022-January 2023) out of 11 months reviewed. Findings

	Included: Review of pocH 100i manual under section 6 states, "To ensure proper functioning of the analyzer, it is necessary to periodically clean and maintain the analyzer. Perform maintenance according to the maintenance schedule detailed in the pocH 100i Instructions for Use. Document maintenance on the maintenance log provided." Review of "pocH 100i Maintenance Log" reveals that daily maintenance was to check instrument status, perform shutdown, and perform quality control. Bi-weekly maintenance was to clean transducer, quarterly maintenance was to clean the waste chamber, and the reagent replacement required to include the lot number, date of expiration, and when put on the machine. There were no maintenance logs filled out since installation of the pocH 100i Hematology analyzer on 03/21/2022. In an interview on 01/18/2023 at 1:10 PM, the Laboratory Manager confirmed that there were no maintenance logs for the Hematology analyzer.
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 review of calibration verification records and interview, the laboratory failed to perform calibration verification every 6 months on the Sysmex pocH 100i Hematology analyzer for 1 (due September 21, 2022) out of 1 calibration verification 6 month period. Findings Included: Review of calibration verification records for the Sysmex pocH 100i Hematology analyzer revealed the calibration verification was performed on 03/21/2022 when the instrument was installed and was due again on 09 /17/2022. No other calibration verifications documentation was provided. The "Certificate of Calibration Verification" stated, "Following installation calibration, the operator is requested to verify the instruments calibration every 6 months or on an 'as needed' basis, and maintain good QC [quality control] practices, to ensure the accuracy of the system." In an interview on 01/18/2023 at 1:20 PM, the Office Manager confirmed that there were no other calibration verifications performed.
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 Hematology quality control records and interview, the laboratory failed to monitor the accuracy and precision over time of quality control (QC) since installation of the pocH 100i Hematology analyzer on 03/21/2022. Findings Included: Review of Hematology QC revealed there was no system in place to monitor the accuracy and precision of QC over time. In an interview on 01/18/2023 at 1:15 PM, the Laboratory Manager confirmed that they were not printing levy jenning charts to monitor the QC for shifts and trends overtime, nor were they enrolled in any peer reviews.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview, the Laboratory failed to perform Quality Control (QC) per their IQCP (Individual Quality Control Plan) for the Respiratory Panel and GI Panel on the Film Array BioFire for 5 (September 2022-January 2023) out of 5 months reviewed, failed to follow manufacturer's instructions on the Piccolo Xpress chemistry analyzer for performing QC for MetLac 12 Panel for 8 (May 2022- January 2023) out of 8 months reviewed, and Basic Metabolic Panel plus testing for 6 (May 2022, June 2022, October 2022-January 2023) out of 6 months reviewed. Findings Included: Review of the IQCP for the Respiratory Panel (Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, SARS-CoV-2, Bordetella parapertussis, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae) and the GI Panel (adenovirus F 40/41, astrovirus, campylobacter, clostridium difficile toxin A/B, cryptosporidium, cyclospora cayetanensis, E. COLI O157, entamoeba histolytica, enteroaggregative E. coli (eaec), enteropathogenic E.

coli (epec), enterotoxigenic E. coli (etec), giardia lamblia, norovirus GI/gii, plesiomonas shigelloides, rotavirus A, salmonella, sapovirus, shiga-like toxin producing e.coli, (stec), shigella/enteroinvasive E. coli (eiec), vibrio, vibrio cholerae, yersinia enterocolitica, enterotoxigenic E. coli (etec) lt/st, shiga-like toxin-producing E. coli (stec) stx1/stx2) signed by the Laboratory Director 01/11/2023 revealed that the external positive and negative QC would be performed monthly. The Laboratory policy prior to the IQCP was to run 2 levels of external QC monthly. Review of QC performed on the Film Array BioFire revealed on instrument 2FA00331 and instrument 2FA00517 revealed no positive and negative control were ran monthly for Respiratory Panel or GI Panel. Review of Patients who had Respiratory Panels tested and reported revealed that Patients were run on the following days for instrument 2FA00517: 09/19/22, 09/20/22, 09/29/22, 10/06/22, 10/13/22, 10/21/22, 10/24/22, 10/31/22, 11/02/22, 11/03/22, 11/04/22, 11/10/22, 11/17/22, 11/20/22, 11/26/22, 11/29/22, 12/08/22, 12/11/22, 12/12/22, 12/13/22, 12/20/22, 12/23/22, 12/26/22, 12/27/22, 12/29/22, 12/30/22, 01/04/23, 01/06/23, 01/07/23, and 01/11/23. Respiratory Panels for Patients were tested and reported on instrument 2FA00331 the following days: 09/20/22, 09/21/22, 09/26/22, 09/27/22, 09/28/22, 09/30/22, 10/03/22, 10/06/22, 10/12/22, 10/15/22, 10/16/22, 10/17/22, 10/18/22, 10/19/22, 10/20/22, 10/21/22, 10/23/22, 10/24/22, 10/25/22, 10/26/22, 10/27/22, 10/29/22, 10/31/22, 11/01/22, 11/02/22, 11/03/22, 11/04/22, 11/06/22, 11/08/22, 11/10/22, 11/15/22, 11/19/22, 11/20/22, 11/21/22, 11/22/22, 11/23/22, 11/24/22, 11/25/22, 11/26/22, 11/28/22, 11/29/22, 11/30/22, 12/02/22, 12/03/22, 12/04/22, 12/05/22, 12/06/22, 12/07/22, 12/08/22, 12/09/22, 12/11/22, 12/12/22, 12/13/22, 12/14/22, 12/17/22, 12/18/22, 12/19/22, 12/20/22, 12/21/22, 12/22/22, 12/23/22, 12/24/22, 12/25/22, 12/26/22, 12/27/22, 12/28/22, 12/29/22, 12/30/22, 12/31/22, 01/01/23, 01/02/23, 01/04/23, 01/06/23, 01/07/23, 01/08/23, 01/10/23, and 01/11/23 for a total of 157 patients reported. Review of Patients who had GI Panels tesed and reported revealed that Patients were run on 3 days (10/22/22, 12/07/22, and 01/13/22) on instrument 2FA00517 and 12 days (10/04/22, 10/22/22, 11/17/22, 12/07/22, 12/10/22, 12/17/22, 12/29/22, 01/07/23, 01/11/23, 01/13/23, 01/14/23, and 01/15/23) on instrument 2FA00331 for a total of 14 Patients reported. In an interview via email on 01/26/2023 at 4:56 PM, the Laboratory Manager confirmed that there were no additional QC ran of the 2 BioFire instruments. Review of the IQCP (signed by the Laboratory Director on 01/11/2023) for the MetLac 12 Panel (Albumin, Calcium, Chloride, Creatinine, Glucose, Lactate, Magnesium, Phosphorus, Potassium, Sodium, Total Carbon Dioxide, and Blood Urea Nitrogen) ran on the Abaxis Piccolo Xpress instrument stated that, "External QC will be tested with each new lot or shipment of reagents." Review of the manufacturer's instructions revealed that the QC is tested "at least every 30 days, whenever laboratory conditions have changed significantly, when training or retraining of personnel is needed, when test results do not match patient symptoms or clinical findings, with each new lot". Prior to the IQCP the Laboratory was following manufacturer's instructions for their policy. Review of external QC for MetLac 12 Panel revealed 2 levels of external QC were not ran for 8 (June 2022 - January 2023) out of 8 months reviewed. There were no other external QC records for the MetLac 12 Panel. Review of Patients who had MetLac 12 Panels tested and reported revealed that Patients were run the following days: 06/17/22, 06/20/22, 07/05/22, 07/07/22, 07/28/22, 08/01/22, 08/27/22, 09/07/22, 10/14/22, 10/21/22, 10/24/22, 10/25/22, 11/01/22, 11/13/22, 11/16/22, 11/21/22, 11/24/22, 11/25/22, 11/26/22, 11/28/22, 11/30/22, 12/06/22, 12/09/22, 12/12/22, 12/18/22, 12/23/22, 12/24/22, 12/26/22, 12/27/22, 12/29/22, 01/04/23, 01/05/23, 01/06/23, 01/11/23, and 01/12/23 for a total of 45 Patients reported. Review of Basic Metabolic Panel Plus (Calcium, Chloride, Creatinine, Glucose, Lactate Dehydrogenase, Magnesium, Potassium, Sodium, Total Carbon Dioxide, and Blood Urea Nitrogen) ran on the Abaxis Piccolo Xpress instrument revealed that there was no IQCP to follow manufacturer's instruction that

	"External QC will be tested with each new lot or shipment of reagents." Review of the manufacturer's instructions revealed that the QC is tested "at least every 30 days, whenever laboratory conditions have changed significantly, when training or retraining of personnel is needed, when test results do not match patient symptoms or clinical findings, with each new lot". Review of external QC for Basic Metabolic Panel Plus revealed that QC was ran on 07/27/22 (High and Low), 08/01/22 (High and Low), and 09/01/22 (High and Low). There were no QC for 6 (May 2022, June 2022, October 2022-December 2022, and January 2023) out of 6 months reviewed. There were no other external QC records for Basic Metabolic Panel Plus. Review of patients who had Basic Metabolic Panel Plus tested and reported revealed Patients were run on the following days: 05/08/22, 05/09/22, 05/17/22, 05/20/22, 05/23/22, 05/27/22, 06/01/22, 06/02/22, 06/03/22, 06/06/22, 06/07/22, 06/10/22, 06/14/22, 06/15/22, 06/16/22, 06/21/22, 06/29/22, 07/01/22, 07/02/22, 07/03/22, 07/11/22, 08/10/22, 08/16/22, 08/25/22, 08/30/22, 09/02/22, 09/05/22, 09/06/22, 09/08/22, 09/13/22, 10/02/22, 10/03/22, 10/05/22, 10/09/22, 10/14/22, 10/28/22, 10/29/22, 10/30/22, 11/02/22, 11/04/22, 11/05/22, 11/15/22, 11/17/22, 11/18/22, 11/19/22, 11/22/22, 11/23/22, 11/24/22, 11/25/22, 11/26/22, 11/29/22, 12/01/22, 12/04/22, 12/05/22, 12/07/22, 12/09/22, 12/12/22, 12/14/22, 12/15/22, 12/16/22, 12/17/22, 12/18/22, 12/19/22, 12/20/22, 12/22/22, 12/23/22, 12/30/22, 12/31/22, 01/01/23, 01/02/23, 01/03/23, 01/09/23, and 01/15/23 for a total of 113 Patients reported. In an interview via email on 01/25/2023 at 2:51 PM, the Laboratory Manager confirmed the findings of the MetLac 12 Panel and Basic Metabolic Panel Plus QC and Patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of Patient results for the BioFire and interview, the laboratory failed to compare the two Film Array BioFire instruments that were being used for Respiratory Panel and GI (Gastrointestinal) Panel testing twice a year 5 (September 2022 - January 2023) out of 5 months reviewed. Findings Included: During the tour of the Laboratory on 01/17/2022 at 1:00 PM Film Array BioFire instruments (serial # 2FA00517 and #2FA00331) were observed. Review of Patient results revealed that both instruments were performing Respiratory Panel (Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, SARS-CoV-2, Bordetella parapertussis, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae) and GI Panel (Adenovirus F 40/41, astrovirus, campylobacter, clostridium difficile toxin A/B, cryptosporidium, cyclospora cayetanensis, E. COLI O157, entamoeba histolytica, enteroaggregative E. coli (eaec), enteropathogenic E. coli (epec), enterotoxigenic E. coli (etec), giardia lamblia, norovirus GI/gii, plesiomonas shigelloides, rotavirus A, salmonella, sapovirus, shiga-like toxin producing e.coli, (stec), shigella/enteroinvasive E. coli (eiec), vibrio, vibrio cholerae, yersinia enterocolitica, enterotoxigenic E. coli (etec) lt/st, shiga-like toxin-producing E. coli (stec) stx1/stx2) testing. No instrument

	to instrument comparison was performed on the instruments. In an interview on 01/17 /2023 at 2:00 PM, the Laboratory Manager confirmed that there were no instrument to instrument comparison performed twice a year.
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 lack of Quality Assurance documents and interview the Laboratory failed to ensure a Quality Assurance program was established since testing began 05/08/2022. Findings Included: There were no Quality Assurance documents in the Laboratory. Interview on 01/18/2023 at 4:30 PM, the Laboratory Director confirmed that there were no Quality Assurance documents available for review.
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 observations, review of manufacturers' instructions, review of temperature charts, and review of calibration verification records, review of maintenance logs, and interview the Laboratory Director failed to provide effective direction over the Laboratory (See D6004), the Laboratory Director failed to maintain a quality control program (See D6020), the Laboratory Director failed to establish a Quality Assurance program (See D6021), and the Laboratory Director failed to ensure quality control was acceptable before Patient testing was performed (See D6025).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, review of temperature

	logs, review of calibration verifications, review of maintenance, and interview the Laboratory Director failed to provide effective direction over the laboratory since 05 /08/2022. Findings Included: The Laboratory Director failed to ensure controls were stored per manufacturer's requirements (BioFire respiratory panel) and failed to ensure room temperature and humidity was documented (See D5413). The Laboratory Director failed to ensure Hematology calibration verification was performed (See D5439). The Laboratory Director failed to ensure Hematology maintenance was documented (See D5429). The Laboratory Director failed to ensure instrument comparisons were performed for the 2 BioFire instruments (See D5775).
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control records and interview the Laboratory Director failed to ensure the quality control (QC) program was established and maintained since 05/08/2022. Findings Included: The Laboratory Director failed monitor Hematology QC for shifts and trends (See D5441). The Laboratory Director failed to follow Individual Quality Control Plan (IQCP) for the 2 Film Array BioFire instruments, and failed to follow manufacturers' instructions on the Abaxis Piccolo Xpress for MetLac 12 panel or Basic Metabolic Panel plus (See D5445).
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of Quality Assurance documents and interview the Laboratory Director failed to ensure a Quality Assurance program was established since testing began 05 /08/2022 (See D5791). Findings Included: There were no Quality Assurance documents in the Laboratory. Interview on 01/18/2023 at 4:30 PM, the Laboratory Director confirmed that there were no Quality Assurance documents available for review.