Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1071563	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
National Institute On Aging Irp/Lci	3001 S Hanover St 5th Floor, Baltimore, MD	

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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the specimen log book, procedure CL-050 Oral Glucose Tolerance Testing (OGTT) Sample Processing and Result Reporting, and interview with the laboratory director, technical consultant, and testing person (TP 1), the laboratory failed to document the date and time the specimen was received in the laboratory. The findings include: 1. The BLSA OGTT log book (Baltimore Longitudinal Study on Aging Oral Glucose Tolerance Test logbook) did not list the received date of the patient specimens. 2. Procedure CL-050 (on pages: 4, 5, 8, 10, 13, and 16) states the requirement for documenting the sample collection date, but the received date is not mentioned. 3. At approximately 1pm, the laboratory director, technical consultant, and TP 1 confirmed that the collection date was being recorded but not the received date.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, technical consultant, and testing person (TP 1), the laboratory failed to have an up-to-date

written procedure manual for the specific procedures used in the National Institue on Aging (NIA) laboratory for the testing person to follow. The findings include: 1. The table of contents did not match the procedures in the manual. TP 1 had to flip through the large notebook in search of procedures the surveyor needed to review. 2. The manual did not include the procedure to record room temperature, refrigerator temperatures, or freezer temperatures for the NIA laboratory. a. There was a procedure for recording the refrigerator/freezer temperatures in the Core Laboratory. b. At approximately 1pm, the laboratory director, technical consultant, and TP 1 of the laboratory being surveyed (the NIA laboratory) stated that the Core laboratory was a separate laboratory and certified under a different CLIA certificate. c. The procedure did not contain a process to record room temperature values. d. The manufacturer room temperature requirement for the Pentra 400 is listed in the user guide in the Appendix on Table 11 as: "Ambient temperature 15-32 degrees centigrade". e. The testing person was recording refrigerator, freezer, and room temperatures on a temperature chart. The chart indicated that 'NU' was to be used for 'Not in use' and a slash or an 'NR' was to be used for 'Not recorded'. The exact meaning of 'Not in Use' and 'Not recorded' was not explained in any procedure that was found in the manual. 3. The manual included a Corrective Action procedure that was described on the front page as belonging to the Core laboratory and was signed by the Core laboratory director. The procedure did not indicate what action to take when temperatures were out of range. There was no procedure in the manual for corrective actions in the NIA laboratory. 4. TP 1 was using a Corrective Action log sheet when there were problems with running samples on the Pentra 400 and the YSI 2900's. There was no procedure in the manual for the use of those Corrective Action log sheets. 5. TP 1 was processing specimens, performing maintenance, running and recording quality controls, operating the instruments, and reporting results from the Pentra 400 and two YSI 2900 instruments. There was no procedure in the manual for the Pentra 400 or YSI 2900's that indicated how those activities should be performed and recorded. 6. The manual contained a procedure entitled, "Reporting Critically High and Low Glucose Results". The procedure referred to the use of the YSI 2300 STAT PLUS glucose analyzer. a. At approximately 1pm, the laboratory director, technical consultant and TP 1 explained that the YSI 2300 STAT PLUS had been replaced by a Pentra 400 and two YSI 2900 instruments and the YSI 2300 had been given to the Core laboratory. b. The procedure indicated under "SCOPE OF PRACTICE" that the document applied to the YSI 2300 STAT PLUS located in the Core Laboratory and operated by Core Laboratory Techs. c. TP 1 provided two examples of critically high glucose results run on the Pentra 400 in the NIA laboratory and had been emailed to the laboratory director. She explained that this was the process that was followed when a critically high glucose was found. There was no procedure in the manual for the process to be followed when a critically high glucose was found on either the Pentra 400 or the YSI 2900. 7. There was a BLSA OGTT DATA log book in which TP 1 was transcribing data from the result sheets generated by the Pentra 400 called the BLSA OGTT SPEC LOG in pencil. On July 25, 2019 the instrument BLSA OGTT SPECIMEN LOG sheet indicated a "C date" of 07/25/2019 for ID number 4941-08. The transcribed "C date" for ID number 4941-08 in the BLSA OGTT DATA log book was 07/24/2019. The transcription error and purpose of the handwritten log was discussed with the laboratory director, technical consultant, and TP 1. They said it was on old procedure from a time when the instrument that had been in use did not have a paper printout and the values had to be transcribed from the screen on the instrument. There was no procedure in the manual for the use of this handwritten log book. 8. Procedure CL-026 entitled Laboratory Quality Control (Q.C.) from the manual stated under: "Policy": All quality control problems must be communicated immediately to the Core laboratory manager. The procedure was signed by the NIA

	laboratory director on 11/22/2015. The laboratory director said that the Pentra 400 and the YSI 2900's were brought into the NIA laboratory in 2017 around the time of the last survey. It was not clear from the written procedure if the procedure was meant for use in the NIA laboratory or the Core laboratory and it had not been updated since the new equipment was put into use.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the MIN/MAX Temperature chart and interview with the laboratory director, technical consultant, and testing person (TP 1), the laboratory failed to document corrective action for the out-of-range refrigerator temperatures during the months of January 2019 to June 2019. The findings include: 1. The MIN /MAX Temperature chart for the laboratory's refrigerator showed temperatures above or below the acceptable range of 2-8 degrees (listed on the chart) for several months in 2019. a. Jan 2019: 20 out 20 days b. Feb 2019: 18 out of 18 days c. Mar 2019: 18 out of 20 days d. Apr 2019: 6 out 22 days e. May 2019: 10 out 21 days 2. The bottom portion of the temperature chart stated "corrective action for out of limits readings to be documented above or reverse side". The reverse side of the chart was blank and there were no corrective actions noted above the statement on the chart. 3. When asked how was the temperature fixed and where is the documentation, TP 1 stated "I fixed the probe but forgot to write down on the back of the log ,when I fixed it" 4. On the temperature chart every month was signed off in the Supervisor Review Column with the same initial and date "06/28/19" Verifying the accuracy of the temperature chart by approved personnel. 5. At approximately 1pm, the laboratory director, technical consultant, and TP 1 confirmed that the corrective actions were not documented.
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 record review and interview with the laboratory director, technical consultant, and testing person (TP 1) there was no written policy by the laboratory director delegating the technical consultant duties to anyone. The findings include: 1. The personnel form filled out by the laboratory before the survey and presented to the surveyors when they arrived on site did not list a technical consultant. 2. TP 1 said that her competency testing was performed by a person other than the laboratory director. 3. The quality assurance reviews of the corrective action forms, temperature charts, quality control documents including the monthly review of the Levy-Jennings plots were all signed by the same person who is not the laboratory director. 4. The qualifications of the person who was performing the technical consultant duties were not on file when the surveyor asked to see them. They were provided during the survey. 5. The delegation statement was not on file when the surveyor asked to see it. It was provided during the survey.