Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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# Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0671907	(X3) Date Survey Completed 09/22/2023
Name of Provider or Supplier University Of Miami Diabetes Research	**Street Address, City, State** 1450 Nw 10th Ave Room 3033, Miami, 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	A recertification survey conducted from 09/07/2023 to 09/22/2023 found the UNIVERSITY OF MIAMI DIABETES RESEARCH clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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: I-Based on observation, review of reagent containers, temperature logs and interview, the laboratory failed to document corrective actions (CA) for 202 days out of 491 days for freezer temperatures that were not within acceptable temperature range as per manufacturer (-20 to -70C) for the storage of the following Quality Controls: Bio-Rad Liquicheck Immunoassay Plus Controls, Bio-Rad Liquicheck Specialty Immunoassay, Bio-Rad Liquid Assayed Multiqual and Bio-Rad Liquicheck Lipids. II-Based on lack of documentation and interview the laboratory failed to document CA for one out of two Bio-Rad Liquid Assayed Multiqual Controls level I and III, that were outside of the mean value 2 standard deviation (SD) for the Cobas c501 module associated to a Cobas 6000 Integra analyzer during 2023 for the analytes Chloride, Sodium and Potassium. Findings included: I-During the laboratory tour on 09/07/2023 at 11:30 AM, the surveyor observed that the laboratory was using the following controls: Bio-

Rad Liquicheck Immunoassay Plus Controls, Bio-Rad Liquicheck Specialty Immunoassay and Bio-Rad Liquicheck Lipids. None of the controls bottle had been labeled with the received date and opened date. When the surveyor reviewed the freezer designated for the control's storage found: one opened box of Biorad Liquicheck Immunoassay Plus Control: Level 1 lot number 85341 and Level 3 with lot number 85343 with expiration date 11/30/2024. An opened box of Biorad Liquicheck Lipid control level 1 with lot number 57261 with expiration date 11/30/2024. None of the boxes had a receiving date. Review of the manufacturer instructions revealed the following statement in the section "STORAGE AND STABILITY" "This product will be stable until the expiration date when stored unopened at -20 to -70C." -Review of "Quality Assurance Program" policy on section "Quality Control" revealed the following "All tests materials are stored as directed by manufacturer." -Review of the Freezer "TEMP-CHEX TEMPERATURE RECORD" revealed an acceptable temperature range of "-10 to -30 C". This temperature range did not meet the storage requirement for the controls. -Review of documented temperature logs from 10/01/2021 to 09/14/2023 revealed the following dates the temperature has not reached the requirement of -20C or colder: 10/07/2021, 10/08/2021, 10/12/2021, 10/15/2021, 10/19/2021, 10/25/2021, 10/26/2021, 10/27/2021, 10/28/2021, 10/29/2021, 11/01/2021, 11/03/2021, 11/05/2021, 11/08/2021, 11/09/2021, 11/10/2021, 11/11/2021, 11/15/2021, 11/19/2021, 11/22/2021, 11/29/2021, 11/30/2021, 12/06/2021, 12/08/2021, 12/09/2021,12/13/2021, 12/16/2021, 12/18/2021, 12/23/2021, 12/28/2021, 12/29/2021, 12/30/2021, 01/03/2022, 01/04/2022, 01/05/2022, 01/06/2022, 01/12/2022, 01/13/2022, 01/14/2022, 01/19/2022, 01/20/2022, 01/24/2022, 01/25/2022, 01/26/2022, 01/27/2022, 01/28/2022, 02/01/2022, 02/02/2022, 02/04/2022, 02/07/2022, 02/10/2022, 02/11/2022, 02/15/2022, 02/16/2022, 02/17/2022, 02/21/2022, 03/04/2022, 03/07/2022, 03/09/2022, 03/14/2022, 03/17/2022, 03/18/2022, 03/25/2022, 03/30/2022, 03/31/2022, 04/04/2022, 04/06/2022, 04/07/2022, 04/08/2022, 04/14/2022, 04/15/2022, 04/18/2022, 04/20/2022, 04/21/2022, 04/26/2022, 04/27/2022, 04/29/2022, 05/03/2022,05/06/2022, 05/09/2022, 05/11/2022, 05/16/2022, 05/17/2022, 06/01/2022, 06/02/2022, 06/03/2022, 06/07/2022, 06/08/2022, 06/09/2022, 06/10/2022, 06/13/2022, 06/17/2022, 06/21/2022, 06/22/2022, 06/27/2022, 06/28/2022, 07/11/2022, 07/14/2022, 07/15/2022, 07/20/2022, 07/27/2022, 08/01/2022, 08/05/2022, 08/11/2022, 08/18/2022, 08/22/2022, 08/23/2022, 08/25/2022, 09/01/2022, 09/22/2022, 09/23/2022, 09/29/2022, 10/03/2022, 10/05/2022, 10/07/2022, 10/14/2022, 10/17/2022, 10/18/2022, 10/27/2022, 10/28/2022, 10/31/2022, 11/01/2022, 11/02/2022, 11/03/2022, 11/04/2022, 11/07/2022, 11/09/2022, 11/11/2022, 11/15/2022, 11/16/2022, 11/18/2022, 11/21/2022, 11/29/2022, 12/05/2022, 12/08/2022, 12/09/2022, 12/12/2022, 12/13/2022, 12/14/2022, 12/15/2022, 12/19/2022, 12/22/2022, 12/23/2022, 12/27/2022, 01/03/2023, 03/05/2023, 01/06/2023, 01/12/2023, 01/13/2023, 01/17/2023, 01/18/2023, 01/19/2023, 01/20/2023, 01/23/2023, 01/24/2023, 01/27/2023, 02/01/2023, 02/10/2023, 02/13/2023, 02/14/2023, 02/15/2023, 02/17/2023, 02/21/2023, 02/23/2023, 02/28/2023, 03/06/2023, 03/08/2023, 03/10/2023, 03/20/2023, 03/21/2023, 03/22/2023, 03/23/2023, 03/24/2023, 03/31/2023, 04/05/2023, 04/06/2023, 04/12/2023, 04/13/2023, 04/18/2023, 04/19/2023, 04/20/2023, 04/26/2023, 04/27/2023, 05/04/2023, 05/10/2023, 05/12/2023, 05/18/2023, 05/26/2023, 05/31/2023, 06/01/2023, 06/02/2023, 06/06/2023, 06/21/2023, 08/07/2023, 08/19/2023, 08/21/202308/30/2023, 09/05/2023, 09/06/2023, 09/11/2023, 09/12/2023, 09/13/2023. -There was no documentation of CA for the days the temperature was outside of the acceptable range. II- Review of "Quality Control Policy" of the procedure manual signed by the laboratory director on 10/17/2019, revealed the following: "Criteria for accepting run. Tolerance limits are set at 2 SD of the mean value, and upgraded as need, i.e. reagent lot change, or after major maintenance. Any control out of the limits will be checked and remedial action pertaining to the specific test will be taken." -

	Review of Cobas c501 analyzer QC instrument printouts two controls levels (I and III) Bio-Rad Liquid Assayed Multiqual Controls lots 45811 and 45813 respectively revealed that in the following dates at least one of the controls was out for Sodium, Chloride and or Potassium analyte: -05/24/2023: control III level was outside of mean 2 SD for Chloride (109.3 mmol/l) and Sodium (146 mmol/l), no CA documented. -06 /09/2023: control III was outside mean 2 SD for Chloride (115.3 mmol/l), no CA documented. -06/15/2023: control III was outside mean 2 SD for Chloride (104.9 mmol/l), Potassium (6.78 mmol/l) and Sodium (140.00 mmol/l), the controls were not repeated, and no CA documented. On this day the laboratory tested proficiency testing samples and received a failed result for Sodium and Chloride. -Review of Levy Jenning charts in the Cobas c501 instrument screen for from 01/01/2023 to 08/31 /2023 for Chloride, Sodium and Potassium controls levels revealed that for Chloride there were 23 days with at least one control outside of the 2 standard deviations, for Sodium there were 13 days with at least one control outside of the 2 standard deviations and for potassium there was 1 days with at least one control outside of the 2 standard deviations. There was no documentation of CA for those days with controls values outside of the mean 2 SD. During an interview on 09/07/2023 at 2:00 PM the testing person confirmed that there was no documentation of the CA for the failure in the control results cited in the days of reference. During a telephone interview on 09 /22/2023 at 2:30 PM, the Testing Person confirmed that temperature records of the freezer used for the storage of the controls were outside of the acceptable temperature ranges in the days listed above and there was no documented CA for those days.
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 documentation and interview, the laboratory Quality Assessment (QA) failed to identify and correct the deficiency of freezer temperature outside of the acceptable range and failed to ensure the laboratory documented the actions for quality controls outside of the acceptable range from 01/01/2023 to 08/31/2023. Findings included: -No documentation that the QA corrected the failure to ensure that the freezer used for the storage of the following Quality Controls: Bio-Rad Liquicheck Immunoassay Plus Controls, Bio-Rad Liquicheck Specialty Immunoassay and Bio-Rad Liquicheck Lipids. Refer to D5781. -Review of QA policy of the procedure manual signed by the laboratory director (LD) on 10/17/2019 revealed that, On Section D-1 it stated "Quality Controls (QC) (samples) are analyzed and documented each day of testing as specified in our procedure manual. Controls results are within acceptable limits before patient testing samples are reported. All QC results are recorded, even if a particular control value does not fall within the acceptable range. Any repeat control or corrective action is documented." -No documentation of corrective actions for controls outside of acceptable range found. Refer to D5781. During an interview on 09/07/2023 at 2:30 PM the testing person confirmed that there was documentation of the QA action to correct the deficiencies listed above.
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 record review and interview with testing person, the Laboratory Director failed to ensure the Quality Assessment corrected the laboratory deficiencies. Refer to D5791.