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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0957235 | (X3) Date Survey Completed 06/27/2024 |
| Name of Provider or Supplier Immunopathogenesis Section | Street Address, City, State 10 Center Drive, Bethesda, 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 |
|---------------------------|--|
| D0000 | A recertification survey was conducted on 06/26/2024, with additional information obtained on 06/27/2024. Standard level deficiencies were cited. |
| D5301 | <p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of specimen logs and interview with the technical supervisor-2 (TS-2), the laboratory failed to have written or electronic requests for patient anticytokine autoantibodies testing from an authorized person for 18 of 18 specimens. Findings included: 1. Review of specimen logs from 04/2024 through 06/2024 included the following specimens received from Frederick, MD without a written or electronic request for testing: Received 04/22/2024 (date process was date aliquoted in Frederick) - CNML085899, "Date Process 3/27/2024" CNML085903, "Date Process 3/27/2024" CNML086143, "Date Process 4/10/2024" CNML086148, "Date Process 4/11/2024" Received 06/10/2024 (isolation date was date aliquoted in Frederick)- CNML086487, "Isolation Date 5/7/24" CNML086490, "Isolation Date 5/7/24" CNML086586, "Isolation Date 5/14/24" CNML086587, "Isolation Date 5/14/24" CNML086632, "Isolation Date 5/15/24" CNML086630, "Isolation Date 5/15/24" CNML086624, "Isolation Date 5/15/24" CNML086748, "Isolation Date 5/21/24" CNML086770, "Isolation Date 5/23/24" CNML086779, "Isolation Date 5/24/24" CNML086835, "Isolation Date 5/31/24" CNML086918, "Isolation Date 6/5/24" CNML086924, "Isolation Date 6/5/24" CNML086944, "Isolation Date 6/6/24" The sample type was an aliquot of plasma from Ethylenediaminetetraacetic acid (EDTA) collection tube processed at Frederick, MD. The specimens were sent to Frederick, MD via Fedex. 2. During an interview on 06/26/2024 at 2:29 pm, TS-2 was unable to provide written or electronic requests for the specimens sent from Frederick, MD for testing. She</p> |

confirmed that the specimens come from everywhere (U.S. and international) but was unable to provide any more information about where the specimens were collected and date/time of collection.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedures and policies, test requisitions, and interview with staff, the laboratory failed to ensure a date and time of collection was solicited on the test requisition to ensure the 48-hour stability for 14 of 14 anticytokine autoantibody specimens. Findings included: 1. Review of the laboratory's procedures and policies did not include a defined specimen stability for anticytokine autoantibody testing. During an interview on 06/26/2024 at 1:28 pm, TS-2 stated that the specimen stability was 48 hours. 2. Review of test requisitions for patients received from 04/2024 through 06/2024 did not include date and time of collection for the following (EDTA and sodium heparin specimens were collected in the hospital): Patient 1 - received 4/16/24 Patient 2 - received 4/16/24 Patient 3 - received 4/22/24 Patient 4 - received 4/29/24 Patient 5 - received 4/29/24 Patient 6 - received 4/29/24 Patient 7 - received 5/1/24 Patient 8 - received 5/6/24 Patient 9 - received 5/7/24 Patient 10 - received 6/13/24 Patient 11 - received 6/18/24 Patient 12 - received 6/18/24 Patient 13 - received 6/18/24 Patient 14 - received 6/23/24 The requisitions included a date/time of order "Release Hold", a date of when to collect the specimen "Collect Specimen On", and a date/time at the top left corner with a barcode. The laboratory was unable to determine the date and time of collection on the test requisition, as required. 3. During an interview on 06/26/2024 at 2:41 pm, TS-1 and TS-2 confirmed that the date/time of collection is not solicited on patient test requisitions.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's procedure, observation, specimen logs, and interview with TS-2, the laboratory failed to include all specimen types accepted and tested by the laboratory in their own written policy for anticytokine autoantibodies. Findings included: 1. Review of the laboratory's written procedure "Plasma Isolation from Human Peripheral Blood" stated, "Note: This protocol assumes the investigator is beginning this with full Green-top (Plasma Tube) BD Vacutainer tubes of human blood (roughly 10 ml). Plasma is not the same as serum." 2. During an observation of specimen processing on 06/26/2024 at 10:02 am, TS-1/TP-1 received one patient specimen (Patient #0) in an EDTA (purple top) blood collection tube (label included 06/26/2024 5:55 am). The test order was for anticytokine autoantibodies. EDTA specimen type was not included as acceptable in the laboratory's written procedure. 3. Review of specimens logs from 07/2023 through 06/2024 included the following documented patient specimen types received and analyzed by the laboratory: 07/2023 - 3 EDTA 08/2023 - 1 EDTA 09/2023 - 1 EDTA 11/2023 - 1 serum and 1 EDTA 12/2023 - 1 EDTA 01/2024 - 3 EDTA 02/2024 - 1 Serum 03/2024 - 4 EDTA 04/2024 - 6 EDTA 05/2024 - 1 EDTA 06/2024 - 14 EDTA The laboratory did not include serum and EDTA specimens as acceptable types for analysis in their own written procedure. 4. During an interview on 06/26/2024 at 1:10 pm, TS-2 confirmed EDTA and serum were specimen types accepted and tested for anticytokine autoantibodies. She confirmed this was not part of their written procedure. II. Based on direct observation, interview with TS-1/TP-1, review of the laboratory's written procedure, and the CMS-116 application, the laboratory failed to define centrifugal revolutions per minute (RPM) in their written procedure for patient specimen anticytokine autoantibodies testing. Findings included: 1. During an observation of specimen processing on 06/26/2024 at 10:02 am, TS-1/TP-1 received one patient specimen (Patient #0) in an EDTA (purple top) blood collection tube for anticytokine autoantibodies testing. TS-1/TP-1 proceeded to place the specimen in a Beckman Coulter Allegra 6KR Centrifuge for 10 minutes at 1,800 RPMs. On 06/26/2024 at 10:15 am, she stated the acceptable RPM range for centrifuging patient specimens is 1,600 - 1,800 RPMs. 2. Review of the laboratory's written procedure "Plasma Isolation from Human Peripheral Blood" stated, "In a centrifuge capable of safely spinning blood tubes, spin the blood at roughly 2000 rpm for 10 minutes at room temperature." The laboratory failed to define the centrifugal RPMs range according to the observation and interview in their written procedure. 3. Review of the laboratory's CMS-116 application total estimated annual test volume was 2,000 for anticytokine autoantibodies. III. Based on interview with staff, review of written procedures, and the CMS-116 application, the laboratory failed to define specimen storage, stability, and transportation conditions in their written procedure for anticytokine autoantibodies testing. Findings included: 1. During an interview on 06/26/2024 at 9:48 am, the technical supervisors stated aliquoted plasma specimens from a Frederick, MD laboratory are sent via courier to the laboratory on dry ice. They stated the specimens sent to Frederick, MD are by FedEx from all over the country and international. The submitters must send specimens within 48 hours for the Frederick, MD laboratory to aliquot and freeze. The laboratory did not define this information in their written procedures. 2. During an interview on 06/26/2024 at 1:28 pm, technical supervisor-2 was unable to provide the following in a written and approved procedure for specimen handling: a) defined stability of plasma (sodium heparin and EDTA) and serum specimens (in interview she stated 48 hours). b) defined storage temperature (room temperature, refrigerated, frozen) with stability of plasma (sodium heparin and EDTA) and serum specimens. c) the defined conditions (temperature, dry ice) of specimen transportation to the

Frederick, MD laboratory and then to the laboratory for testing in Bethesda. d) the defined stability of specimens from the time of collection to the Frederick, MD laboratory and then to the laboratory for testing in Bethesda. 3. Review of the laboratory's CMS-116 application total estimated annual test volume was 2,000 for anticytokine autoantibodies.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on interview with a testing person, review of policies and procedures, and specimen logs, the laboratory failed to provide written instructions to Frederick, MD laboratory that send aliquoted plasma specimens for anticytokine autoantibodies testing. Findings included: 1. During an interview on 06/27/2024 at 1:15 pm, a testing person at the Frederick, MD laboratory was asked whether Immunopathogenesis laboratory in Bethesda, MD provides written instructions for specimen handling. She stated the laboratory has sent some information in emails. The testing person stated specimens are received via FedEx, they are centrifuged, aliquoted for the plasma and stored in a freezer (observed temperature of -144C). Once the laboratory in Bethesda requests them, they are sent via a courier on dry ice with a list of the patients (no test orders included). She stated at one point they were receiving green top tubes, but the Bethesda laboratory has requested for EDTA tubes only. 2. During an interview on 06/27/2024 at 1:30 pm, the testing person at the Frederick, MD laboratory was unable to provide the above information in writing. The testing person provided their own policy (Document ID: NMLQCP001) that included specimen rejection criteria of >48 hours. This was applied to all specimens received in their laboratory. 3. The laboratory failed to provide written instructions for specimen handling to the Frederick, MD laboratory with the following information: a) specimen labeling b) specimen storage and stability c) conditions for specimen transportation d) specimen processing (centrifugal speed/time) e) specimen acceptability and rejection criteria 4. Review of specimen logs from 09/2023 through 06/2024 included 48 patient specimens received from the Frederick, MD laboratory for testing.

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:

I. Based on direct observation, manufacturer's instructions, and interview with technical supervisor-3 the laboratory failed to set freezer temperature ranges in

accordance with storage requirements of the manufacturer for 3 of 3 Thermo Scientific Pierce EDC reagents. Findings Included: 1. During a tour of the laboratory on 6/26/24 at 10:31am, the freezer labeled 'Holland Lab Freezer #32 (-20C)' was observed with a temperature reading of -28C, and three Thermo Scientific Pierce EDC reagents, Lot YK378257, manufacturer storage requirement -25C to -15C, stored inside. 2. In an interview within the laboratory on 6/26/24 at 10:31am, technical supervisor-3 corroborated the observational finding of incorrect storage freezer temperatures for the reagents. II. Based on direct observation, review of specimen logs, laboratory's procedures, and interview with technical supervisor-2, the laboratory failed to monitor and document refrigerator temperatures for 2 of 2 refrigerators. Findings Included: 1. During a tour of the laboratory on 6/26/24 at 10:15 am, a Thermo Scientific refrigerator was observed with no documentation of temperature monitoring with the following stored: a. One vial - Invitrogen Goat anti-Human IgG (0.5 mg/ml), Lot number 2626357, "opened 6/4/24", Store at 2-8C b. One vial - IL-23 quality control (QC), thawed 5/14/24, Store at 4C c. One vial - [34] IFNA QC, thawed 5/14/24, Store at 4C d. One vial - IL-17A QC, thawed 5/14/24, Store at 4C e. One vial - [26] IFNA QC, thawed 5/14/24, Store at 4C f. One vial - [29] GM-CSF QC, thawed 5/14/24, Store at 4C g. One vial - MagPlex - C Microsphere 029 (1.0 ml), Lot number B76386, opened "11/20/23", Store at 2-8C h. One vial - MagPlex - C Microsphere 027 (1.0 ml), Lot number B95856, opened "11/20/23", Store at 2-8C i. Bio-Rad Bio-Plex Assay Buffer, 1x, 50 ml Batch 64468089, expiration 2026-02-15, Store at 2-8C, "opened 6/14/24" j. Bio-Rad Bio-Plex Wash Buffer, 750 ml Batch 64551819, expiration 2027-04-24, Store at 4C, "opened 6/14/24" k. One box - Bio-Plex Amine Coupling Kit, Control 64529047, expiration 2025-09-02, Store at 4C, "opened 6/27/23" 2. During a tour of the laboratory on 6/26/24 at 10:31am, one unlabeled refrigerator for use, located in room 11S258A, was observed with no documentation of manual or electronic temperature monitoring, with the following reagents stored inside: a. 1 box of Bio-Plex Calibration Kit, Batch 64596274, manufacturer storage requirement 4C b. 1 box of Bio-Plex Validation Kit 4.0, Batch 64548417, manufacturer storage requirement 4C 3. 54 patients' samples were run, since the Bio-Plex reagents located in the refrigerator of Room 11S258A were in use (in use as of 3/22/2024). 4. A review of the laboratory's procedure titled "Quality Assurance Plan" revealed the following on page 3: "Equipment Monitoring All instruments such as freezers, refrigerators, and incubators are monitored manually or electronically by alarm system. Refrigerator temperature should be between 2C and 8C ..." 5. In an interview within the laboratory on 6/26/24 at 10:46am, technical supervisor-2 corroborated that there was no active temperature monitoring (both manual or electronic) of the refrigerators in use. 43232 III. Based on review of manufacturer's instructions, direct observation, interview with staff, and review of the CMS-116 application, the laboratory failed to monitor and document room 11S258A temperature and humidity where the Bio-Plex System 200 system was stored and used for anticytokine autoantibodies testing. Findings included: 1. Review of the Bio-Plex 200 operator's manual (manufacturer's instructions, page 36) stated, "Operating temperature 15-30C (59-86F); Operating humidity 20-80%, noncondensing" 2. During a tour of the laboratory on 06/26/2024 at 11:23 am, the Bio-Plex 200 system was stored and operated in room 11S258A with no documentation of monitoring room temperature and humidity, as required by the manufacturer's instructions. 3. During an interview on 06/26/2024 at 11:23 am, the technical supervisors confirmed room 11S258A was not monitored and documented for temperature and humidity. 4. Review of the laboratory's CMS-116 application total estimated annual test volume was 2,000 for anticytokine autoantibodies. IV. Based on review of manufacturer's instructions, direct observation, interview with staff, and review of the CMS-116 application, the laboratory failed to monitor and document temperature and humidity

where Phosphate Buffered Saline and the Bio-Plex Pro Wash Station were stored. Findings included: 1. Review of the Bio-Plex Pro Wash Station operator's manual (manufacturer's instructions, page 23) stated, "Environmental Operation 15C to 35C (59F to 95F) ...Relative Humidity Operation 20-80% noncondensing." 2. During a tour of the laboratory on 06/26/2024 at 11:28 am, the following were observed, and temperature and humidity was not monitored and documented: Bio-Plex Pro Wash Station on a counter and one bottle of Phosphate Buffered Saline Without Ca and Mg by Quality Biological (Lot number 725578, expiration date 9/2025), Store at 15-30C, on a shelf (used for plasma constitution). 3. During an interview on 06/26/2024 at 11:28 am, the technical supervisors confirmed the area in which the Bio-Plex Pro Wash Station and Phosphate Buffered Saline were stored was not monitored and documented for temperature and humidity. 4. Review of the laboratory's CMS-116 application total estimated annual test volume was 2,000 for anticytokine autoantibodies.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on direct observation, manufacturer's instructions, and confirmed in an interview with the TS-3, the laboratory failed to ensure 2 of 2 supplies were not expired and available for patient testing. Findings included: 1. In direct observation, on 6/26/24 at 11:03am, the following were expired inside of the refrigerator located in Room 11S258A: a. 1 bottle of Bio-Rad Bio-Plex Assay Buffer, Control 210012124, manufacturer expiration date 2019-03-13. b. 1 bottle of Bio-Rad Bio-Plex Sample Diluent, Control 350001978, manufacturer expiration date 2017-10-30. 2. In an interview within Room 11S258A on 6/26/24 at 11:04am, the TS-3 confirmed that the supplies were expired.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory records, and interview with technical supervisor-3, the laboratory director failed to specify in writing the responsibilities and duties for 1 of 1 Technical Supervisors and 2 of 2 General Supervisors. Findings Included: 1) Review of CMS-209 form revealed one Laboratory Director (LD), Clinical Consultant (CC), Technical Supervisor, two General Supervisors and one Testing Personnel (TP) listed. 2) A

review of the laboratory personnel responsibilities labeled under the document title 'Corrective Action Plan', revealed no written responsibilities and duties for the TS and GS roles. 3) During an interview on 6/26/24 at 10:09 am in the office room, technical supervisor-3 corroborated that there were no role designations for the Technical Supervisor and General Supervisor.