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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D1024514 | (X3) Date Survey Completed 03/29/2022 |
| Name of Provider or Supplier Purine Metabolic & Immunodeficiency Lab | Street Address, City, State 235 Sands Building 303 Research Drive, Durham, NC | |
| 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 |
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| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with laboratory director (LD) and general supervisor (GS #1) 3/29/22, the laboratory failed to discard reagents and/or solutions and supplies that had deteriorated and/or exceeded their expiration date. Findings: At approximately 11:30 a.m. surveyor observed multiple reagents and/or solutions and supplies in the laboratory refrigerator that had deteriorated and/or exceeded their expiration date. For example: 1. One small paper box labeled "National Institutes of Health" with a receipt date of 2/22/12. Inside the box were small bottles labeled "Adagen Lot #1119A" and "EZU-2279 Lot #1097". 2. One bottle of "Bovine Serum Albumin" receipt date of 1/7/16. 3. One container of "ADA1 Assay Mix" preparation date of 10/1/18 and expiration date of 4/1/19. Interview with LD and GS #1 at approximately 2:30 p.m. confirmed the laboratory refrigerator had many reagents, solutions and supplies that had deteriorated and/or exceeded their expiration dates. The LD and GS #1 stated that none were used for patient testing and were used for research purposes at one time. They also stated any reagents, solutions or supplies that had deteriorated and/or exceeded their expiration dates would be discarded.</p> |
| D6102 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate</p> |

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 review of testing personnel (TP) training and competency records and interview with LD 3/29/22, the LD failed to ensure training for 2 of 2 recently hired TP was documented. Findings: Review of TP #4 and TP #5 training and competency records revealed the following: 1. TP #4 was hired in October of 2021, competency was assessed in March of 2022. The records contained no documentation of training. 2. TP #5 was hired in July of 2019, competency was assessed in February of 2020, March of 2021 and March of 2022. The records contained no documentation of training. Interview with LD at approximately 1:30 p.m. confirmed the records failed to document TP #4 and TP #5 training. He stated that it had been so long since any new TP were employed that they failed to realize training must be documented. He also stated the TP were extensively trained and have had their competency assessed.