Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2102433	12/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Reference Laboratories Llc	7924 Forest City Rd, Orlando, 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	Recertification survey was conducted on August 1, 2023 to December 14, 2023. Genesis Reference Laboratories clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Condition was not met: D5400 - 493.1250 - Analytic Systems
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, record review, and interview, the laboratory failed to store Covid-19 positive, Covid-19 Mastermix, Covid-19 No template control, Luna One Step Reaction mix, Fast Tag Advanced Master Mix, Luna Enzyme Mix, and Ultra Distilled Water, IDT E Ph 7.5 as per the manufacturer's temperature guidelines (D5413).The laboratory failed to document positive, negative and internal controls to confirm if test passed or failed for the following PCR test urinary tract infection (UTI), sexual transmitted infections (STI), H. pylori, Respiratory Pathogen Panel (RPP) and antibiotic resistance (ABR) from 6/1/2021 to present.
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 observation, record review, and interview, the laboratory failed to store Covid-19 positive, Covid-19 Master mix, Covid-19 No template control, Luna One Step Reaction mix, Fast Tag Advanced Master Mix, Luna Enzyme Mix, and Ultra Distilled Water, IDT E Ph 7.5 as per the manufacturer's temperature guidelines. Findings Included: On 8/3/2023 at 11:30 AM, a tour of the laboratory revealed a refrigerator labeled M2 and a freezer labeled M1. Reagents contain in M2 were: Covid-19 positive control read store "-40 C to -16 Celsius (C)." Covid-19 Master mix read" store 40 C to-16 C." Covid-19 No template control read " store -40 C to -16 C." Reagents contained in M1 were: Fast Advance Master mix read stored at 2 C to 8 C. Luna Probe One-Step read stored at -20 C. Luna Enzyme mix read stored at -20 C. Ultra-Pure Distilled Water read store at 15 to 30 C. IDtE ph. 7.5 read store at room temperature. Review of Reagent Management Policy signed by the laboratory director on 6/5/2023 read," all materials must be stored as outlined by the manufacturer." Review of 2023 M2 temperature log read "2 to 8 C" storage. Review of 2023 M1 temperature log read "-15 to -25 C" storage and temperature log revealed the following: 4 out of 31 days for 5/2023 temperature was above -20 C. 6 out of 31 days for 6/2023 temperature was above -20 C. 3 out of 31 days for 7/31 temperature was above -20 C. On 8/14/2023 at 4:00 PM, laboratory director confirmed the laboratory failed to store Covid-19 positive, Covid-19 Master mix, Covid-19 No template control, Luna One Step Reaction mix, Fast Tag Advanced Master Mix, Luna Enzyme Mix, and Ultra Distilled Water, IDT E Ph 7.5 as per the manufacturer's temperature guidelines.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, and observation, the laboratory failed to document positive, negative and internal controls to confirm if test passed or failed for the following PCR test urinary tract infection (UTI), sexual transmitted infections (STI), H. pylori, Respiratory Pathogen Panel (RPP) and antibiotic resistance (ABR) from 6/1/2021 to present. Findings: Review of test menu revealed the following: ABX targets: Ampicillin (ampC) Carbapenem (VIM) Carbapenem (KPC) Carbapenem (IMP-7) Carbapenem (OXA-48_1) Carbapenem (OXA-48_2) Carbapenem (NDM_1) Carbapenem (NDM_2) ESBL (TEM) ESBL (CTX-M group1) ESBL (SHV) ESBL (CTX-M group2) Fluoroquinone (QnrA) Fluoroquinone (QnrB) Macrolide (ErmA)

Macrolide (ErmB) Macrolide (mefA) Methicillin (mecA) Vancomycin (vanA2) Vancomycin (vanB) UTI Panel Enterobacter cloacae Enterococcus faecalis Escherichia coli Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma hominis Proteus mirabilis Providencia stuartii Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus saprophyticus Streptococcus agalactiae Ureaplasma urealyticum Candida albicans Candida glabrata Candida krusei Candida lusitaniae Candida parapsilosis Candida tropicalis STI Trichomanas vaginalis Ureaplasma urealyticum Chlamydia trachomatis Neisseria gonorrhoeae Mycoplasma genitalium Mycoplasma hominis (Thermo) Gardnerella vaginalis Mycoplasma genitalium Mycoplasma hominis Trichomonas vaginalis Ureplasma urealyticum Candida albicans Candida auris Candida glabrata Candida krusei Candida lusitaniae Candida parapsilosis Candida tropicalis Chlamydia trachomatis Herpes Simplex Virus 1 Herpes Simplex Virus 2 HPV 16 HPV 18 HPV 31 HPV 33 Neisseria gonorrhoeae Treponema pallidum Mpox RPP: Influenza A Parainfluenza Virus 1 Influenza A/H3 Parainfluenza Virus 2 Influenza B Influenza C Influenza A/H1-2009 Parainfluenza Virus 3 Parainfluenza Virus 4 Human Coronavirus NL63 Human Parechovirus Human Coronavirus HKU1 Human Metapneumovirus A/B Human Coronavirus 229E Human Coronavirus OC43 Adenovirus Human Rhinovirus Bocavirus Human Enterovirus MERS SARS Respiratory Syncytial Virus A Chlamydia pneumoniae Klebsiella pneumoniae Legionella pneumophila Legionella pnuemophila/longbea Mycoplasma pneumoniae Streptococcus pneumoniae Bordetella bronchiseptica/parapertussis Bordetella pertussis Haemophilus influenzae B Haemophilus influenzae Staphylococcus aureus mecA Bordetella holmesii Coxiella burnetii Moraxella catarrhalis Pneumocystis Jirovecii COVID-19 Panel H. Pylori Panel On 8/1/2023 at 9:00AM, lab tour showed: Area 1A is the Plating room. Area 1B is the kingfisher plate. Area 2 is 5 quant studio 5 location. Review of ABR quality controls excel spreadsheet forms from 5/1/2022 to present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of H. Pylori quality controls excel spreadsheet forms from 3/6/2023 to present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of RPP quality controls excel spreadsheet forms from 5/1/2022 to present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of Covid quality controls excel spreadsheet forms from 5/1/2022 to present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of STI quality controls excel spreadsheet forms from 5/1/23 7/31 /2023 to present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of UTI quality controls excel spreadsheet forms from 6/1/2023 to 6/9/2023 present revealed there were no dates listed for positive control runs for Quant studio instrument, and no documentation for negative and internal control runs. Review of SOP # MOL 19.0 SOP # MOL 19.0 - QUALITY MANAGEMENT - QUALITY CONTROL (MOLECULAR) signed by laboratory director on 6/7/2023 read, "A) QM /QC Data. All QM/QC data will be reviewed monthly. In the event that an unacceptable trend is discovered in the data from an instrument or assay, the necessary corrective action should be taken to rectify the problem as soon as possible. All corrective actions taken should be documented accordingly. All QM/QC records will be retained for a period of no less than 2 years. 4. Test Controls PCR Based Assays RNA/DNA Control The RNA/DNA control is added in each run (before or after nucleic acid isolation) which will. produce amplification signals. The purpose of the RNA/DNA control is to assure that the assay. is working properly. The RNA

	/DNA controls are prepared from either cell line derived. nucleic acids, patient samples or prepared by manufacturers. Stock RNA/DNA (aliquots) that have gone through the nucleic acid isolation process are stored frozen at -18 C or colder. Internal Control Internal Control such as monitoring for RNaseP amplification may also be used. RNase P is co-extracted and amplified from all patient samples as an internal control to assess the extraction efficiency and specimen quality. This also serves as an extraction control to ensure. that samples resulting as negative contain nucleic acid for testing. Note: RNaseP may not amplify in all samples due to sampling conditions. No Template Control (NTC) The NTC is used for the detection of contaminating nucleic acid within a given PCR assay. All necessary reagents are present within the tube(s), but no sample is ever deliberately added. (water in place of sample). Therefore, any amplification product present is highly suggestive of contamination. Based on the severity of the contamination, the results can be interpreted with caution or discarded and the assay repeated. Use an NTC for every run starting from nucleus. acid isolation if possible or if contamination is suspected." No statement on how often controls will be run and how to monitor controls in quality assurance policy for molecular. On 8/3 /2023 at 3:15 PM, the laboratory director stated as of 7/1/2021 to current date the following tests have been run for PCR: 461,506 for COVID, 120 for H. polyuria ,1616 for STI 7385 for UTI and 6277 for RPP. On 8/3/2023 at 4:00 PM testing personnel confirmed no document ion positive, negative and internal controls for to confirm if test passed or failed for the following PCR test urinary tract infection (UTI), sexual transmitted infections (STI), H.pylori, Respiratory Pathogen Panel (RPP) and antibiotic resistance (ABR) from 6/1/2021 to present.