Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0665877	05/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Hospital	2951 Maple Ave, Zanesville, OH	

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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, test orders, complaint document review, and interviews with the Laboratory Services Manager (LSM), and Support Staff Manger (SSM), the laboratory failed to meet the applicable preanalytic system(s) requirements. Finding Includes: 1. The laboratory failed to establish and follow policies and procedures for test requests. (Refer to D5305) 2. The laboratory failed to establish and follow policies and procedures for specimen submission and handling. (Refer to D5311) 3. The laboratory failed to establish and follow policies and procedures for preanalytic quality assessment. (Refer to D5393)
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 record review, an interview with the Laboratory Services Manager (LSM), and an electronic mail (email), the laboratory failed to ensure test requisitions included the time of specimen collection, when appropriate. This deficient practice had the potential to affect all patients tested under three of three specialties which include Microbiology, Chemistry, and Hematology from 01/03/2020 through 04/04/2022. Findings Include: 1. Review of a urinalysis report log titled "ODH-GHLab_UA Statistics-02_14_22" received 04/05/2022 at 11:48 AM via email found seven out of 36 specimens were received and analyzed with the same collection and receipt times. 2. Review of the "Laboratory General Checklist" provided during the complaint investigation found the following statement: "GEN.40750 Requisition Elements 7. Date of specimen collection, and if appropriate, time of collection." 3. The inspector requested documentation of collection times for the identified seven out of 36 specimens that indicated the same collection and laboratory receipt times from the LSM. The LSM was unable to provide the requested information. The interview occurred 04/04/2022 at 9:40 AM. 4. A follow-up email received 04/05/2022 at 11:48 AM from the LSM stated if there were no collection times written on the requisition or specimen containers, the specimen collection time defaults to the time the specimen was received in the laboratory.
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: Based on document review, an interview with the Laboratory Service Manager (LSM), and an electronic mail (email), the laboratory failed to establish and follow a written procedure for the transport conditions of specimens. This deficient practice had the potential to affect all patient specimens transported from off-site laboratories and tested in three of three specialties which include Microbiology, Chemistry, and Hematology from 01/03/2020 through 04/04/2022. Findings Include: ITEM 1 1. Review of the laboratory's policy and procedure manual titled, "Genesis Healthcare System Departmental Policy & Procedure Guide", did not find any mention of a policy and procedure for the conditions and handling of specimens during transport. 2. The inspector requested a policy and procedure for specimens transported to the laboratory from an offsite location which includes specimen transport conditions, from the LSM. The LSM verified there was no policy and procedure which included the specimen transport conditions and was unable to provide the requested

	information. The interview occurred on 04/04/2022 at 11:45 AM. 3. A follow-up email received from the LSM on 04/13/2022 at 4:00 PM stated there was no criteria established for specimen transport from offsite locations. ITEM 2 Based on document review, an electronic mail (email), and an interview with the Laboratory Service Manager (LSM), the laboratory failed to establish and follow a written procedure for specimen acceptability and rejection. This deficient practice had the potential to affect all patients tested in six of six specialties which include Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immunohematology, and Pathology from 01/03 /2020 through 04/04/2022. Findings were as follows: 1. Review of the laboratory's policy and procedure manual titled, "Genesis Healthcare System Departmental Policy & Procedure Guide", did not find any mention of specimen acceptability and rejection. 2. The inspector requested a policy and procedure for acceptability and rejection of specimens from the LSM via email 04/11/2022 at 12:14 PM. The LSM provided the policy and procedure titled, "Specimen Integrity Guidelines", via email on 04/13/2022 at 4:00 PM. 3. Review of the laboratory's policy and procedure titled, "Specimen Integrity Guidelines", provided via email on 04/13/2022 at 4:00 PM, found the following statement: "PURPOSE: To provide guidelines for the management of "sub-optimal" laboratory specimens with regard to hemolysis, icterus, and lipemia. Procedure will define the mechanism that will be used to notify the requesting physician of the sample condition." 4. The LSM was unable to provide a policy and procedure for acceptability and rejection of specimens, that included all variables to specimen acceptability and rejection, such as labeling, tube type, quantity of specimen, broken or leaking containers, transport and storage temperature requirements other than with regard to hemolysis, icterus, and lipemia. .
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on document reviews, quality assessment documentation, and an interview with the Laboratory Services Manager (LSM), the laboratory failed to review the effectiveness of corrective actions taken to resolve problems, and revise policies and procedures to prevent recurrences of problems for all preanalytic systems quality assessment activities. This deficient practice had the potential to affect three out of six patients tested in the specialties of Chemistry, Hematology, and Virology from 01/01 /2022 through 03/12/2022. Findings Include: 1. Review of the laboratory's policies and procedures titled " Quality Assurance Monitoring" did not find any instructions for the assessment of quality in the preanalytic systems which included the effectiveness of corrective actions taken to resolve problems, and revise policies and procedures to prevent recurrences of problems. 2. Review of the "Lab Incident Report Log_Turnaround Times" provided via electronic mail (email) on 04/11/2022 at 11:54 AM found the following three out of six preanalytic patient event dates and identification numbers: 01/01/2022; PE-22-01552; "Pt had a urine specimen sent to lab to be run for a UA and tox screen. At 0517 the tox screen was placed in process, but as of 0635, no results for tox screen were posted. UA results were posted on chart at 0619. This LPN called lab to check status tox screen at 0635. Lab states that the

	specimen "was not on the line" and was going to check the line where the UA was run to see if the specimen was there as it is not currently running for a tox screen and was not able to be located. James states that results would be posted approx 15 min once sample was started" 01/15/2022; PE-22-01692; "Aptt ordered as stat, lab was seen collecting the specimen at 2200. Labs were still not resulted at 2320. Lab had not sent the specimen or ran it as a stat specimen." 03/12/2022; PE-22-02196; "Called lab for estimated time on result of COVID, Flu and RSV. Was told by lab member that it was started at 2:06 and there would not be a result until at least 4:30-5am. This results in a delay of care for the patient. Called back to lab approximately 5 minutes later and lab member stated that the test resulted 5 minutes ago and would be posted now" 3. The Inspector requested the laboratory's quality assessment review of the effectiveness of corrective actions taken to resolve problems, and any revisions to policies and procedures that were made to prevent recurrences of problems. This request was made via email on 04/11/2022 at 12:14 PM for the above listed laboratory issues. On 04/13 /2022 at 4:00 PM via email the LSM provided screenshots of the laboratory's "Patient Event Review Details" with the following comments attached: Review 03198 "Urine tox order was linked to the Rapid COVID accession number, instead of routine Urinalysis order. Emergency department contacted the Lab at 06:35, the Lab located the specimen, and the Urine tox results reported at 06:58." Review 02896 "The details provided in the event description do not appear to be accurate.. See the screen shot below. There were no orders in Epic for a 22:00 STAT APTT." Review 03625 "Reviewer unable to verify TAT details stated in the event description. It is unclear to the reviewer why lab would have stated such an exaggerated turn around time. Swab was collected at 01:53, received in the lab at 02:06, and resulted at 03:40." 4. The LSM was unable to provide the laboratory's quality assessment review of the effectiveness of corrective actions taken to resolve problems, and any revisions of policies and procedures made to prevent recurrences of problems for all preanalytic systems quality assessment activities as requested on 04/13/2022 at 4:00 PM.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on document review, and an interview with the Laboratory Services Manager (LSM), the laboratory failed to have a system in place to ensure test results were accurately sent to the final report destination. This deficient practice had the potential to affect all patients tested in five out of five specialties which include Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Pathology from 01/01/2020 to 04/04/2022. Findings include: 1. Review of the laboratory's policy and procedure manual titled "Genesis Healthcare System Departmental Policy & Procedure Guide" failed to find a policy to ensure test results were accurately sent to the final report destination. 2. On 04/04/2022 at 12.15 PM during a complaint investigation, the LSM stated all laboratory results were automatically uploaded to an electronic medical

	records system titled EPIC. Linked within EPIC is a list of hospital system physicians. After result reviews, the system will automatically upload test results to the patient chart which is accessible by the ordering physician. The LSM also stated if a physician is not electronically linked to EPIC, manually faxed results are sent. The LSM further stated a physician may request to be called on the requisition to report test results. 3. The inspector requested tracking of the electronic and manually reported test results from 2020 to the inspection date of 04/04/2022 from the LSM. The LSM confirmed the laboratory did not track result reporting and did not have a policy and procedure to ensure the test results were accurately sent to the final report destination and was unable to provide the requested documents. The interview occurred 04/04/2022 at 12:15 PM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Services Manager (LSM), the laboratory failed to establish and follow written policies and procedures, and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect all patients tested in five of five specialties which include Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Pathology from 01/01/2020 to 04/04/2022. Findings Include: ITEM 1 1. Review of the laboratory's policy and procedure titled "Quality Assurance Monitoring" provided on the date of the inspection found the following statement: "PROCEDURE: 2. Monitors are selected which include pre-analytical, analytical, and post-analytical aspects of patient care and, in particular, those relating to activities that are high patient impact and/or are high risk for error." 2. The inspector requested documentation of the monitoring of completeness and timeliness of reporting results from the LSM for 2020 to the inspection date of 04/04/2022. 3. The LSM stated the laboratory does not check the completeness and timeliness of results reported and was unable to provide the requested documents. The interview occurred 04/04/2022 at 1:05 PM. ITEM 2 Based on record review and an interview with the Support Services Manager (SSM), the laboratory failed to establish and follow written policies and procedures, and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect all patients tested in two of two specialties which include Microbiology, and Chemistry from 01/01/2020 to 04/04/2022. Findings Include: 1. Review of the laboratory's policy and procedure titled "Quality Assurance Monitoring" provided on the date of the inspection found the following statement: "PROCEDURE: 2. Monitors are selected which include pre-analytical, analytical, and post-analytical aspects of patient care and, in particular, those relating to activities that are high patient impact and/or are high risk for error." 2. The inspector requested post-analytical tracking of urine stat turn-around times, or the number of STAT applicable specimens received without the necessary collection time stamps that are high patient impact and/or are high risk for error from 2020 to the inspection date of 04/04/2022. 3. The SSM stated the laboratory does not document or monitor the urine stat turn-around times, or the number of stat applicable specimens received without the

	necessary collection time stamps that are high patient impact and/or are high risk for error. The SSM was unable to provide the requested documents. The interview occurred 04/04/202 at 1:05 PM.