

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0372981	(X3) Date Survey Completed 01/16/2026
Name of Provider or Supplier Ascension Genesys Hospital Lab	Street Address, City, State One Genesys Parkway, Grand Blanc, MI	
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	<p>. The purpose of this unannounced survey was for complaint MI00155126. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements). Standard deficiencies were cited.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, observations, and interviews with the blood bank lead and emergency department nurse #3, the specimen collection staff failed to follow specimen collection and labeling policies for 1 of 2 collections observed and 1 of 1 blood bank specimens rejected on 1/16/26. Findings include: 1. A review of the laboratory's "Specimen Labeling, 8110" policy revealed a section stating, "1. Information that must be on the label of every tube/container: a. Patient's first and last name b. Second patient identifier. This can be any of the following: i. Date of Birth ii. Social Security number iii. Driver's License number iv. Health Insurance policy number v. Convalescent Center record number vi. Unique client identification number (research subject ID #) c. Date and time of collection d. Phlebotomist identification i. Genesys Hospital Staff: Computer User ID (i.e. ejeffr3 or hfh0123) ii. Non-Genesys phlebotomist: Initials (i.e. mrv or spk) 2. Blood Bank Specimens for the purposes of pre-transfusion testing the only acceptable Second Patient Identifier is: a. Date of Birth, or b. Social Security # a. Not: It is preferred that all Blood Bank specimens be</p>

labeled in this manner, including ABO/Rh, Type/Screen, Rhogam Evaluation, and Direct Antiglobulin (DAT) testing." 2. The surveyor observed one unlabeled pink-top tube filled with blood in the biohazard trash in the blood bank on 1/16/26 at 11:08 am. 3. An interview on 1/16/26 at 11:30 am with the blood bank lead confirmed the specimen had not been labeled in accordance with the policy listed above and the specimen was rejected. 4. A review of the laboratory's "Blood Collection Tubes & Order of Draw, 8140" policy indicated the order in which blood tubes are to be drawn are as follows: 1. Blood Culture "BacTec Blood culture bottle or Yellow top Isolator Tube" 2. Blue Top "Greiner- Sodium Citrate" or "BD- Sodium Citrate" 3. Navy "BD- Trace metal serum. No additive" 4. Red Top "Greiner- Clot Activator" or "BD- No Additive" 5. Gold Top "Greiner- Clot Activator/Gel" or "BD- Gel Separator" 6. Green Top "Greiner- Lithium Heparin" or "BD- Lithium Heparin" 7. Green Top "Greiner- Sodium Heparin" or "BD-Sodium Heparin" 8. Lavender/Pink/Tan "EDTA Anticoagulant" 9. Gray "Potassium Oxalate/Sodium Fluoride" 10. Yellow Top "Acid Citrate Dextrose Solution A (ACDA)" 11. "Quantiferon-TB Gold Plus Kit" 5. The surveyor observed emergency department nurse #3 perform a venipuncture blood collection on 1/16/26 at 2:20 pm. The tubes were drawn in the following order: 1. Green top 2. Blue top 3. Lavender top 6. An interview on 1/16/26 at 2:45 pm with emergency department nurse #3 confirmed the green top tube was drawn prior to the blue top tube.