Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257657	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northside Gwinnett Hospital	1000 Medical Center Blvd, Lawrenceville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) complaint survey was completed on July 2, 2019. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's policies and procedures, and interview with the blood bank supervisor, the laboratory failed to report blood bank occurrences for distributed blood or blood products as required by the Food and Drug Administration (FDA). The findings include: 1. The facility did not follow their Error Management policy 705-011 for reporting blood bank errors, variances, and accidents to the FDA. Policy guideline states "crossmatch unit tag or label had incorrect or missing information.". The laboratory did not report on 5/5/19 that a crossmatch unit tag was missing information and the sample had identification errors. 2. The blood bank supervisor confirmed on 7/2/19, at 11:00 AM, in the conference room, that the laboratory was not reporting all blood bank errors, variances, and accidents for blood and blood products.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the

	laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of the Immunohematology records, patient records, and interviews with the laboratory's blood bank supervisor and laboratory director, the laboratory failed to meet applicable requirements in specialty of Immunohematology. (Refer to D5553)
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's polices and procedures and interview with the blood bank supervisor, the laboratory failed to address and document problems that occurred when a breakdown in communication arose between the nursing staff and the laboratory for emergency release of blood. The findings include: 1. The laboratory's protocol for emergency release of blood indicates that the laboratory must have a "statement signed by the requesting physician indicating that the clinical situation was sufficiently urgent enough to require the emergency release of blood". 2. The nursing staff's protocol indicates that only a verbal order to the blood bank for the emergency release of blood is required. 3. The laboratory's protocol conflicts with the nursing staff's protocol for the authorization request for the emergency release of blood for a verbal or written confirmation. The conflicting protocols for the authorization of emergency blood release confirms a breakdown in communication between the nursing and laboratory departments. 4. The blood bank supervisor confirmed on 7/2/19, at 11:00 AM in the conference room, that the laboratory's protocol for emergency release conflicts with the nursing staff's protocol for emergency release.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory personnel records and interview with the blood bank supervisor (BBS), it was determined that the laboratory failed to assess employee competency for the blood bank supervisor for the specialty of Immunohematology. The findings include: 1. The laboratory had no record of a competency assessment for the BBS for the 2017 and 2018 for the specialty of Immunohematology. 2. A supervisory performance assessment was performed for the BBS in 2018 but did not encompass laboratory testing competency for Immunohematology. 3. The BBS confirmed on 07/01/19, at 11:30 AM, in the

	conference room, that a competency assessment was performed by the Technical Supervisor but she did not have access to those records.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) policy, and interview with the blood bank supervisor (BBS), the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory for the specialty of Immunohematology. Th findings include: 1. The laboratory is performing QA, but it does not encompass all facets of the laboratory's technical and non-technical functions for the blood bank. 2. The QA for the laboratory did not address and correct problems identified with blood bank such as: incomplete emergency release forms, transfusion start and end times, and review of deviations from the SOP forms from April 2019 to May 2019. 3. The BBS confirmed on 07/01/19, at 11:30 AM, in the conference room, that the laboratory is performing QA but did not address and correct the problems identified with the specialty of Immunohematology.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's standard operating procedures (SOP) and interview with the blood bank supervisor, the laboratory failed to follow their procedure for deviation from the SOP for the specialty of Immunohematology. The findings include: 1. The laboratory procedure for deviation from the SOP stated that "There must be documentation of notification and approval by the Transfusion Service Medical Director or designee prior to the deviation." 2. The laboratory's deviation log revealed that a deviation from the SOP was performed on 4/29/19 and was not authorized by the Medical Director until 4/30/19. The laboratory supervisor reviewed the deviation on 5/26/19. 3. The blood bank supervisor confirmed on 7/1/19, at 11:30 AM, in the conference room, that the laboratory had not been following their procedure for having an authorized signature from the Transfusion Service Medical Director or designee before a deviation was performed for the specialty of Immunohematology.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f)

	(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of the blood bank emergency release forms and interview with the blood bank supervisor, the laboratory failed to have an authorized signature before or after release of blood or blood products. The findings include: 1. 2 out of 15 emergency release forms were missing authorization signatures from the requesting physician from April 2019 through May 2019. 4 out of 15 were missing or did not have transfusion monitors. 2. The laboratory's protocol for emergency release of blood indicates that the laboratory must have a "statement signed by the requesting physician indicating that the clinical situation was sufficiently urgent enough to require the emergency release of blood". 3. The laboratory must comply with FDA regulation 21 CFR 606.160 (b)(3)(v) that the "emergency release of blood, including signature of requesting physician obtained before or after release;". 4. The blood bank supervisor confirmed on 7/2/19, at 11:00 AM, in the conference room, that the laboratory had not been following their procedure for following FDA guidelines requiring an authorized signature before or after the emergency release of blood or blood products.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on interviews with the laboratory director (LD) and the blood bank supervisor (BBS), the laboratory director failed to employ a sufficient number of laboratory testing personnel (TP) for the specialty of Immunohematology. The findings include: 1. An interview with the BBS revealed that there is only one laboratory testing personnel performing testing in blood bank for the week night shift and the weekend shifts. 2. The LD and BBS confirmed on 7/2/19, at 11:00 AM, in the conference room, that the laboratory does not have an adequate number of testing personnel for the specialty of Immunohematology.