

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0203761	(X3) Date Survey Completed 02/06/2026
Name of Provider or Supplier Einstein Medical Ctr Montgomery	Street Address, City, State 559 W Germantown Pike, East Norriton, PA	
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	An unannounced complaint investigation was conducted February 5 through February 6, 2026. The facility was found to be NOT in compliance with the following CLIA condition: 42 CFR 493.1100 Facility Administration
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).</p> <p>This CONDITION is not met as evidenced by: Based on review of facility and laboratory policies, laboratory records, and confirmed in staff interviews, the facility failed to meet the requirements for transfusion services, as evidenced by: 1. The facility failed to document all transfusion-related activities. Refer to D3015. 2. The facility failed to follow their own policy to ensure positive blood product recipient identification. Refer to D3023. 3. The facility failed to retain blood product documentation for five of twelve blood products issued on 01/03/2026. Refer to D3035.</p>
D3015	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103</p> <p>A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility transfusion forms, facility policies, patients' transfusion</p>

records, and confirmed in interview with the Laboratory Director, the facility failed to document all transfusion-related activities for seven of eleven patients receiving emergency release blood and blood component transfusions. Findings: 1. The facility utilized a form titled "Blood Bank Transfusion Record" called the "Transfusion Tag". This record provided an area for patient demographic information, blood product information that included "Donor ABO/Rh, Unit Number, Component, and Special Testing". The form included the following check boxes "To be completed by the Transfusionist": " ...Verify patient ID bracelet corresponds in name, DOB, and medical record number to information on Blood Identification label and this record. Blood Group and Rh on this slip match the unit and blood identification label. Blood unit number on the slip matched the number on front of unit and the blood identification label ..." The form provided an area for the signature of the "RN /Physician" (Transfusionist) and for the signature of the "Verifier". The form also provided an area to record "Vital signs, Time, Temp, Pulse, Resp, Pressure" and initials for the person. Times to record patient vital signs were "pre-transfusion, 15 minutes post start, 1 hour, 2 hours, 3 hours, and post-transfusion". 2. The facility also utilized two versions of a "Request for Blood Products" form. a. One version of the form titled "Request for Blood Products" included areas to document patient demographics, type of product requested, special orders, blood component unit numbers, patient type, component Type, issued date and time, initials of the person who issued the component and initials of the person who retrieved the component from the Blood Bank. b. The second version of the form titled "Request for Blood Products To Be Sent in the Tube" included areas to document patient demographics, completed by initials, blood component unit number, product requested, special orders, initials/date/time of person sending the component, the tube station number the component was sent to, date/time received and the initials of the person who received the component from the tube system. 3. The facility policy titled "Blood Administration" stated " ...B. Transfusionist Responsibilities 1. Verification For inpatient/Emergency Department 2 RN's must verify and one verifier must hang the blood. For Procedural areas there must be two verifiers (RN of physician or Licensed Perfusionist) who are deemed competent in the verification process. All blood administered in a procedural area is considered emergent ...c. Verify the patient's ABO /Rh on the Blood Bank Transfusion Record e. Correlate the blood donor unit number on the front of the unit of blood, the Blood Identification Label, and the Blood Bank Transfusion Record at the patient's bedside ...h. Sign, date, and time the Blood Bank Transfusion Record at the patient's bedside ...3. Monitoring ...Vital signs will be taken 15 minutes after starting the transfusion, then every hour until blood is transfused and documented on the Blood Bank Transfusion Record ...D. Complete the Blood Bank Transfusion Record ...and place the original in the patient's medical record ..." The facility policy titled "Emergency Transfusion" (BB07-001 2.1) stated " ...6.0 Additional Notes ...6.2 Each unit of blood and transfusion tag attached to the blood that is issued to the patient that was uncrossmatched must have an orange 'Uncrossmatched Blood' sticker applied to the unit." 4. Review of eleven patient blood /blood product transfusion records for emergency release (11/24/2025 through 01/03 /2026) revealed the following in which the facility failed to document all transfusion-related activities: a. 11/24/2025 Patient 103502430 W180225178883 RBC and W180225215112 RBC; Issued to ER 11/24/2025 at unknown time. No "Request for Blood Products" form provided. Vitals signs documented were pulse and pressure at pre-transfusion, 15 minutes post start and post-transfusion. No other vital signs were documented on the Blood Transfusion Record. b. 11/29/2025 Patient 103635804 W182225426942 RBC and W182225442273; Issued to ER 11/29/2025 at 1336 per the "Request for Blood Products" form. No vital sign information was documented on the Blood Transfusion Records. c. 11/30/2025 Patient 101245412 W182225453341

RBC; Emergency release requested 11/30/2025 1836 per the "Emergency Transfusion Request" form. No "Request for Blood Products" form provided. No patient identification verifiers' signatures were documented on the Blood Transfusion Record and none of the required information was completed by the transfusionist. d. 12/11/2025 Patient 101419375 W181725414087 RBC; Issued 12/11/2025 0307 per the "Request for Blood Products" form. No patient identification verifiers' signatures were documented on the Blood Transfusion Record and none of the required information was completed by the transfusionist. W182225371497 FFP; Issued 12/11/2025 0428 per the "Request for Blood Products" form. No patient identification verifiers' signatures were documented on the Blood Transfusion Record and none of the required information was completed by the transfusionist. W182225444327 RBC; Issued 12/11/2025 0510 per the "Request for Blood Products" form. Transfusionist and Verifier signatures were the only documentation on the Blood Transfusion Record. No other required information was completed on the form. W182225459169 RBC; Issued 12/11/2025 0510 per the "Request for Blood Products" form. Only the transfusionist signature was documented on the Blood Transfusion Record. No verifier's signature present and no vital sign information was documented on the Blood Transfusion Record. W182225456703 RBC; Issued 12/11/2025 0510 per the "Request for Blood Products" form. Transfusionist and Verifier signatures were the only documentation on the Blood Transfusion Record. No other required information was completed on the form. e. 12/14/2025 Patient 102982756 W180725196508 RBC and W182225471503 RBC; Issued 12/14/2025 0955 per the "Request for Blood Products" form. Vital signs were documented at pre-transfusion and post-transfusion. No other vital signs were documented on the Blood Transfusion Record. f. 01/03/2026 Patient 101353023 W182125384730 RBC and W182125384720 RBC Emergency release of blood components on 01/03/2026 at unknown time. No "Request for Blood Products" form provided. For W182125384730, pre-transfusion vital signs were the only vital signs documented on the Blood Transfusion Record. No other vital signs were documented on the form. For W182125384720, no vital signs were documented on the Blood Transfusion Record. g. 01/03/2026 Patient 100797456; Blood Type O positive W186825150038LR1 RBC; Issued 01/03/2026 1319 per the "Request for Blood Products to be Sent in the Tube" form. W182225467735 RBC; Issued 01/03/2026 1410 per the "Request for Blood Products to be Sent in the Tube" form. W182225480250 RBC and W181325385671 RBC; Issued 01/03/2026 1450 per the "Request for Blood Products to be Sent in the Tube" form. W182225449693 FFP and W182225863500 PLT Apheresis; Issued 01/03/2026 1530 per the "Request for Blood Products to be Sent in the Tube" form. For each of the six Blood Transfusion Records listed above, no patient identification verifiers' signatures were documented on the form and none of the required information was completed by the transfusionist. Patient 100797456 also received: W186825150038LR2 RBC W186825150023 RBC W182225863507 PLT Apheresis W182225470180 RBC W182225466255 RBC No "Request for Blood Products to be Sent in the Tube" forms were provided for these five blood components. Each of the Blood Transfusion Records had no patient identification verifiers' signatures documented on the form and none of the required information was completed by the transfusionist. Patient 100797456 also received W1827 25 232366 RBC which was type A positive. Issued 01/03/2026 1521 per the "Request for Blood Products to be Sent in the Tube" form and crossmatched for Patient 101115906. No Blood Transfusion Record was provided for this blood component. 5. In an interview on 01/05/2026 at 12:10 pm, the Laboratory Director stated that each unit was issued with a "Blood Transfusion Record" and confirmed the facility failed to document all transfusion related activities. Word Key: ID=Identification DOB=Date of birth RN=Registered Nurse RBC=Red Blood Cells FFP=Fresh Frozen Plasma PLT=Platelet Temp=Temperature Resp=Respiration

(a)(3)(ii) Immunoematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

This STANDARD is not met as evidenced by:

Based on review of facility policy, blood transfusion records, and confirmed in an interview with the Laboratory Director, the facility failed to retain requests for blood product documentation for five of twelve blood products issued on 01/03/2026. Findings: 1. The policy titled "Issuing Blood and Blood Products Through the Pneumatic Tube" (BB08-006 1.1) stated " ...3.0 Procedure ...3.3 Fill out the Request for Blood Products to be sent in Tube form ...3.8 When the blood or blood components are received on the floor the person removing the blood or blood component from the tube will complete the Request for Blood Products to be sent in Tube form and return it back to the Blood Bank through the pneumatic tube. 3.8.1 If the Request for Blood Products to be sent in the Tube form is not returned to the Blood Bank within 30 minutes of issue, call the floor and make sure they have received the blood from the pneumatic tube system and to get them to return the Request form back to the Blood Bank." 2. Review of transfusion records for Patient 100797456 revealed this patient was transfused with 12 blood components on 01/03/2026. The blood components were issued through the pneumatic tube system. W186825150038LR1 RBC, W182225467735 RBC, W182225480250 RBC, W181325385671 RBC, W182225449693 FFP, W182225863500 PLT Apheresis, and W182725232366 RBC issued 01/03/2026 per documentation on the "Request for Blood Products to be Sent in the Tube" form. Patient 100797456 also received the following blood components. W186825150038LR2 RBC, W186825150023 RBC, W182225863507 PLT Apheresis, W182225470180 RBC, and W182225466255 RBC. No "Request for Blood Products to be Sent in the Tube" form was provided for these five blood components. The facility was asked to provide the "Request for Blood Products to be Sent in the Tube" form for these five blood components. No documentation was provided. 3. In an interview on 02/05/2026 at 12:10 pm, the Laboratory Director confirmed the findings.

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 review of facility policies, patient medical records, and confirmed in an interview with the Laboratory Director, the laboratory failed to have a system in place to identify a breakdown in communication between the laboratory and persons authorized to place immunoematology test orders. Findings: 1. Review of laboratory and facility policies revealed the following: a. The laboratory policy titled "Emergency Transfusion" (BB07-001 2.1) stated " ...1.0 Principle ...When blood is released before pretransfusion testing is complete, the records must contain a signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of such blood ...5.2 The ER and OR departments have blank "Emergency Blood Release" forms which ideally should be signed by the

ordering physician and given to the Blood Bank personnel at the time emergency units are requested or when the units are picked up from the Blood Bank ..." b. The laboratory policy titled "Exsanguination Protocol" (BB07-004 2.1) stated " ...1.0 Purpose To enable the rapid provision of red blood cells, FFP/FP24 and Platelets in a predetermined ratio for transfusion in cases of massive blood loss ...This protocol is distinct from "Emergency Release" of uncrossmatched blood as it triggers the release of blood and components in predetermined ratios ...3.3 When the exsanguination protocol is initiated a runner will be dispatched to the Blood Bank to retrieve the blood and blood products. The pneumatic tube will not be used ..." c. The facility policy titled "Exsanguination Protocol, MS.009.00" stated " ...C. Responsibilities 1. Attending Physician or physician involved in resuscitation a. Identify the need for activation of Exsanguination Protocol. B. Ensure proper notification for Exsanguination Protocol initiation to Blood Bank ...2. Nursing ...c. Assigns a runner to pick up the Exsanguination Packs from the Blood Bank ...3. Blood Bank ...c. Assembles Protocol Pack for immediate delivery to patient care area ...4. Runner Goes to Blood Bank and takes the released Exsanguination Protocol pack to the patient care area ..." 2. Review of the medical records revealed Patient 100797456 was admitted to the emergency department on 01/03/2026 at 1256. The Blood Bank received a "Emergency Transfusion Request" form and a "Request for Blood Products to be Sent in the Tube" form. W186825150038LR1 (RBC) was tubed to the emergency department (ED) at 1312 and received by ED personnel at 1318. The Blood Bank received a second "Request for Blood Products to be Sent in the Tube" form. W182225467735 (RBC) was tubed to the ER at 1402 and received by ED personnel at 1410. The Blood Bank received a third "Request for Blood Products to be Sent in the Tube" form. W182225480250 (RBC) and W181325385671 (RBC) were tubed to the ED at 1430 and received by ER personnel at 1450. The Blood Bank received a fourth "Request for Blood Products to be Sent in the Tube" form. W182225449693 (FFP), W182225863500 (PLT Apheresis), and W182725232366 (RBC) were tubed to the ER at 1522 and received by ED personnel at 1530. Patient 100797456 also received the following blood components. W186825150038LR2 RBC, W186825150023 RBC, W182225863507 PLT Apheresis, W182225470180 RBC, and W182225466255 RBC. No "Request for Blood Products" form was provided for these five blood components. The Blood Bank received the another "Request for Blood Products to be Sent in the Tube" form for Patient 101115906. Crossmatched unit W182725232366 (RBC) was tubed to the ED at 1520 and received by ER personnel at 1521. Patient 100797456 received Unit W182725232366 which was type A positive. The patient's blood type was O positive. 3. Review of Patient 100797456 medical record titled "ED Physician Record" stated " ...01/03/2026 13:32:21 and unit of blood started ...01/03/2026 13:34:42 ...massive transfusion protocol attempted to be initiated, however there is significant {SIC} and getting blood product including platelets and FFP by blood bank ...01/03/2026 15:00:01 ...At this time, patient remains hypertensive ...with massive transfusion protocol ..." Review of Patient 100797456 medical record titled "ED Supervisory Addendum Note" stated " ...Date of Service 01/03/2026 12:56:10 Medical Decision Making ...Massive transfusion protocol then initiated ...At this time, we will continue massive transfusion protocol ..." The Emergency Department failed to communicate to the Blood Bank the initiation of "massive transfusion protocol" for Patient 100797456. 4. In an interview on 01/03/2026 at 11:49am, the Laboratory Director (LD) was asked if the ED notified the Blood Bank of a "massive transfusion protocol". The LD stated the Blood Bank was not notified of an initiation of a massive transfusion. The LD was asked how emergency release of uncrossmatched blood or the "Exsanguination Protocol" was requested. The LD stated that both were verbal requests followed by a statement signed by the requesting physician. The LD was asked if the request for emergency release or the exsanguination protocol could be

ordered through the facility's laboratory information system (LIS). The LD stated the only way to place the orders is verbally. In an interview on 01/03/2026 at 12:25pm, the Senior Director of Regulations was asked to provide the massive transfusion protocol referenced in the ED medical records. An "Exsanguination" Protocol was provided. The facility did not have a protocol titled "Massive Transfusion Protocol". Also, in the interview on 01/03/2026 at 12:25pm, the LD stated that the Blood Bank treated all requested blood and blood products to Patient 100797456 as "Emergency Release" and that all blood products were tubed to the ED. No products were picked up from the Blood Bank. This confirmed the breakdown in communications between the Emergency Department and the Blood Bank.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(b)(3)(4)

(b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory personnel records and confirmed in interview with the General Supervisor, the General Supervisor failed to evaluate and document the performance of one of two testing persons (TP) responsible for immunohematology testing at least semiannually during the first year of patient testing. Findings: 1. The laboratory submitted CMS-209 form listed two testing persons responsible for high complexity immunohematology testing. 2. Review of personnel records on 02/06/2026 revealed the following for Testing Person-2: Date of Hire: 08/21/2024 and "Annual" Competency Assessment performed by the GS on 10/24/2025. 3. In an interview on 02/06/2026 at 9:24am, the GS was asked to provide documentation of a second competency assessment for TP-2 during the first year of patient testing. No documentation was provided.