



Quality Excellence Overview

May 2021



2021 CBER Guidance List

Each year CBER releases a list of guidance topics they are considering for the current year. The list includes topics that currently have no guidance, topics where updates may be made to the current guidance, and topics for which CBER may finalize a draft guidance. This list is not all inclusive and it does not guarantee that that topics listed will be addressed.

Blood and Blood Components Guidance Documents CBER plans to issue in 2021:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry • Collection of Platelets by Automated Methods; Guidance for Industry
- Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Issued January 2021 and updated February 2021)
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry
- Compliance Policy Regarding Donation Suitability Requirements; Draft Guidance for Industry

Information from our Technical Services Supervisor

LifeServe implemented new IRL turnaround times effective **Saturday, May 1st, 2021**.

IRL turnaround for a workup request is measured from sample receipt in our Reference Laboratory to the verbal report provided by our Immunohematology Reference Technologist. IRL turnaround for antigen typed units is measured from order receipt in our Reference Laboratory to shipment of units by our Product Management Department. We are initiating updates to our TAT following an analysis of our turnaround metrics. Our metrics indicate that we consistently complete the requested testing significantly faster than our previously posted TAT. Updating our expected turnaround will allow our customers to select the most appropriate order status based on our most current turnaround practices. For example, Routines requests were previously a TAT of 5 days but in actuality these are completed within 48 hours.

I want to highlight a valuable but underutilized functionality of the date/time priority option in BloodHub. Date/Time orders are an asset when used for outpatients with a scheduled transfusion or when your patient has a defined surgical schedule. This function allows you to specify the exact date/time products are needed and allows our team to use the date/time provided to maximize efficiencies and workflow to meet all customer expectations.

Customers can also send segments from units in their inventory to accompany the patient sample for a potential crossmatch. Two segments should be sent per unit, ensuring segments are labeled with the unit number. When a unit from your inventory is crossmatch compatible, your transfusion TAT is reduced as the transport time for units from LifeServe to your facility is eliminated. We recommend sending twice the number of segments for how many units are requested. For example, if I want 2 units crossmatched, I would send segments from 4 units in my inventory. Our team can help advise you on a case-by-case basis.

Immunohematology Workups

Order Status:	Completed within:
STAT	8 hours
ASAP	18 hours
Routine	48 hours
Date/Time	As specified

Antigen Negative Requests

Order Status:	Completed within:
STAT	2 hours (3 hours if requested during on-call timeframe)
ASAP	4 hours
Routine	6 hours
Date/Time	As specified

- * *Quoted TAT excludes molecular testing. Results for molecular DNA profiles are expected within 1 week of specimen receipt.*
- * *LifeServe may exceed the above quoted TAT in circumstances of unforeseen complications navigating complex antibodies or when difficult antigen profiles are requested. LifeServe will communicate delays and update customers with estimated timeframe.*

Rachel Muhs, MLS (ASCP)
Technical Services Supervisor
LifeServe Blood Center
rachael.muhs@lifeservebloodcenter.org
(515) 309-4947