



STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT
NEW LABORATORY TEST ORDER AND PROCEDURE FOR PATIENTS RECEIVING DARATUMUMAB

Description:	A new lab order and a new procedure have been developed to address serological testing complications caused by a drug called Daratumumab (Darzalex). The drug is used to treat some multiple myeloma patients.
Implementation Date:	May 9, 2018
Performing Locations:	<p>Click on the boxes that apply:</p> <p><input type="checkbox"/> Annie Penn Hospital <input checked="" type="checkbox"/> Moses Cone Hospital <input type="checkbox"/> Med Center at High Point <input checked="" type="checkbox"/> Wesley Long Hospital <input type="checkbox"/> Women's Hospital <input checked="" type="checkbox"/> Alamance Regional</p>
Affected Locations:	<p>Click on the boxes that apply:</p> <p><input checked="" type="checkbox"/> Annie Penn Hospital <input checked="" type="checkbox"/> Moses Cone Hospital <input checked="" type="checkbox"/> Med Center at High Point <input checked="" type="checkbox"/> Wesley Long Hospital <input type="checkbox"/> Women's Hospital <input checked="" type="checkbox"/> Alamance Regional <input checked="" type="checkbox"/> Mebane</p>
Affected Departments:	<p>Click on the boxes that apply:</p> <p><input checked="" type="checkbox"/> Blood Bank <input type="checkbox"/> Cytology <input type="checkbox"/> Flow Cytometry <input type="checkbox"/> Histology <input type="checkbox"/> Microbiology <input checked="" type="checkbox"/> Phlebotomy <input type="checkbox"/> Point of Care <input type="checkbox"/> Rapid Response Lab <input type="checkbox"/> Respiratory Therapy <input type="checkbox"/> Specimen Processing</p>

Specimen Type:	6cc Pink Top Tube for Blood Bank
Updated Clinical Lab Procedures:	<p>Alamance Procedure: TRM-719 Daratumumab</p> <p>Greensboro/Reidsville: New Procedure for WL, MC and APH: 7891 CH - Guidelines for transfusing patients taking Daratumumab (Darzalex). (Final version available the week of May 13th)</p>
Retired Clinical Lab Procedures:	NA
Notification to Client:	<p>Click on the boxes that apply: <input type="checkbox"/> Section Not Applicable <input checked="" type="checkbox"/> Memo Needed</p> <p>Distribution of Memo: <input checked="" type="checkbox"/> Medical Staff Oncologists <input type="checkbox"/> Allied Health Professionals (PA, Nurse Practitioners) <input type="checkbox"/> Anesthesia <input type="checkbox"/> Annie Penn (Primary Source Physicians) <input type="checkbox"/> Dentist <input type="checkbox"/> Emergency Department/Urgent Care Centers <input type="checkbox"/> Family Practice <input type="checkbox"/> Infectious Docs #ID Docs (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam) <input type="checkbox"/> OB/GYN <input type="checkbox"/> Pathology <input type="checkbox"/> Pediatricians <input type="checkbox"/> Psych <input type="checkbox"/> Radiology <input type="checkbox"/> Surgery <input type="checkbox"/> #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager) <input checked="" type="checkbox"/> Pharmacy - Send to DeAnne Brooks & Jim Hasspacher & Adam Peele <input type="checkbox"/> #IM Residents <input type="checkbox"/> Kim Helsabeck <input type="checkbox"/> Phlebotomy Managers and Supervisors <input type="checkbox"/> Point of Care: Sheila, Kim & Marty</p>
Accreditation Section:	<p>Click on the boxes that apply: <input checked="" type="checkbox"/> Section Not Applicable <input type="checkbox"/> CAP Test menu change needed</p>

	<input type="checkbox"/> CMS Analyte form change needed <input type="checkbox"/> Proficiency Testing surveys changes needed or ordered
Laboratory IT section:	<p>Click box and type needed changes/additions:</p> <input type="checkbox"/> Section Not Applicable <input checked="" type="checkbox"/> LIS changes <p>05/08/2018: PTTYP (Pre-treatment Phenotype) The test code has been moved to Cone Health Link and SunQuest Production.</p> <input type="checkbox"/> Reference range change/addition <input type="checkbox"/> Technical Failure change/addition <input type="checkbox"/> Critical Value change/add <input type="checkbox"/> Text comments needed <input type="checkbox"/> Specimen collection instructions <input type="checkbox"/> Need to monitor TAT <input type="checkbox"/> CPT code for tests(s)
Technical Staff Update:	<p>Daratumumab (Darzalex) is a drug used to treat multiple myeloma. After a patient receives Daratumumab by infusion, the drug binds to CD 38 on RBCs (both patient and reagent) causing positive indirect antiglobulin tests. The Daratumumab-mediated positive indirect antiglobulin tests may persist for up to 6 months after the last Daratumumab infusion. If a Type and Screen is performed after infusion of Daratumumab blood bank techs may see a positive antibody screen, panagglutination with reagent panel cells, and incompatible AHG crossmatches. The patient's auto control and DAT may or may not be positive. The Daratumumab that is bound to reagent RBCs interferes with the detection of alloantibodies in the patient's plasma. Given these testing complications, current laboratory recommendations include performing a baseline Type and Screen and RBC Phenotype prior to the initiation of Daratumumab treatment.</p> <p>A new laboratory order was developed in CHL and SunQuest. It is called <u>Daratumumab Pretreatment RBC Phenotype (PTTYP)</u>. The order includes a Type and Screen and a Pre Treatment RBC Phenotype. Testing should be ordered and completed prior to initiation of treatment with the drug to minimize compatibility testing delays and provision of phenotypically matched or crossmatch compatible blood.</p>

STOP Initiator:	Teresa Wright, Esther Ingle, Shelley Lawson
Alamance Medical Director Signature:	Quality Department will obtain signature: <i>Joshua B. King MD 5/9/18</i>
Greensboro/Reidsville Medical Director Signature	
Mebane Medical Director Signature	<i>M. O'Leary 5/9/2018</i>

STOP Initiator:	Teresa Wright, Esther Ingle, Shelley Lawson
Alamance Medical Director Signature:	Quality Department will obtain signature:
Greensboro/Reidsville Medical Director Signature	<i>John Petrucci, MD</i> 5/9/18
Mebane Medical Director Signature	



TO: CHCC Providers and Pharmacists

FROM: John Patrick, MD, Adam Peele, PharmD, Tara Rubinas MD

DATE: May 9, 2018


SUBJECT: Darzalex (daratumumab) Type and Screen & RBC phenotype testing

Per the FDA labeled prescribing information, "Daratumumab binds to CD38 on red blood cells and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum."

Current laboratory recommendations include performing a "type and screen" and "RBC phenotype" prior to the initiation of daratumumab treatment. This testing will better allow the blood bank to provide cross match compatible blood and minimize testing delays should your patient require red cell transfusion.

The oncologists will be able to place the lab orders for the "type and screen" and "RBC phenotype" within the daratumumab CHL pre-treatment cycle plan.

SunQuest Label Showing New PTTYP Test Code

Y305000096	123456789	MAJO
05/09/2018 0630	TESTING,LAB	
123456789 W1568		
TESTING,LAB		
Y305000096	Y305000096	07/15/1986 M
05/09/2018 0630	W1568	MCBB
123456789 W1568	05/09/2018	0630
TESTING,LAB	0 PINK-BB	PTTYP *

PTTYP includes Ask at Order Entry test with DARATP auto answer = DARA treatment protocol

Result Entry

Patient **123456789 TESTING,LAB** Hospital **MC**

Dept	Acc#	Order Code	Test Code	Results	QA Flags
BB	W1568	PTTYP	%PI	DARATP	

Test %PI PHYSICIAN INSTRUCTIONS Result

Text type

Composed Text

Preliminary

Final

Auto Fill

Display Prior Results

Result code lookup

Display Correction

Delete all text

Load default text

HIS Order

668 A006150147-0

Save

Cancel

Help

**PTTYP Order in SQ Blood Order Processing (BOP)
Shows Type and Screen (TYSCR) and
Pre-Daratumumab Phenotype (PTTYP)**

213229 TEST,CANADA Soc Sec # _____ DOB 03/09/2013 (

ABO/Rh _____ RC Units Transf _____ Last Transf _____

AS Sum _____ EXM Elig _____

Order Selection Information (8)

Acc. #	Order	Modifier	Collected	Received	CID	CID RD/T	Compnt.	UO	IS
T1637	TYSCR		050818 1225	050818 1226	Y305000094	05/08/2018,...	RCG	H...	
					Y305000093	05/08/2018,...			
					Y305000095	05/08/2018,...			
T1638	PTTYP		050818 1225	050818 1226	Y305000093	05/08/2018,...			

Type and Screen – Tech adds Problem (PB) test in BOP. Results with ;DARA and Tab

213229 TEST,CANADA Soc Sec # _____ DOB 03/09/

ABO/Rh _____ RC Units Transf _____ Last Transf _____

AS Sum _____ EXM Elig _____ Order Loc _____ CHCC _____ Dx (0) _____

Antigens/Antibodies Problems Comments Transfusion Attributes

TYPE AND SCREEN Delta tests HGB:12.0*

Component RED CELLS Collect 05/08/2018 1225 Receive 05/08/2018 1226

Specimen testing

Test	Description	Result
EXX	SAMPLE EXPIRATION	05/11/2018
RN	ARM BAND NUMBER	P98765
UO	UNITS ORDERED	<<DO NOT REPORT>>
CON...	XM INDICATOR	<<DO NOT REPORT>>
HCK	HISTORY CHECK	IN FILE NO
ABR	ABO/RH(D)	O-POS
AS	ANTIBODY SCREEN	NEG
PB	PATIENT PROBLEM INFO	PATIENT RECEIVED DARATUMUMAB

Example of Resulted Patient Phenotype

13229	TEST,CANADA	Soc Sec #	DOB 03/09/2013 (5Y)
BO/Rh O-POS	RC Units Transf	Last Transf	
S Sum NEG	EXM Elig (Hx)	Order Loc	CHCC Dx (0)

1. Antigens/Antibodies
2. Problems
3. Comments
4. Transfusion Attributes

Antigens/Antibodies

Problems DARA - PATIENT RECEIVED DARATUMUMAB

Comments

Transfusion Attributes

Patient Specimen (5)
Allocation (6)
Units (7)
Information (8)

PRE TREATMENT RBC PHENOTYPE Delta tests

Component None Collect 05/08/2018 1225 Receive 05/08/2018 1226

Specimen testing

Test	Description	Result
AGI	PT AG TYPE	NEGATIVE FOR KELL ANTIGEN-POSITIVE FOR E ANTIGEN-POSITIVE FOR e ANTIGEN-POSITIVE FOR C ANTIGEN-NEGATIVE FOR c ANTIGEN-POSITIVE FOR DUFFY A ANTIGEN-POSITIVE FOR DUFFY B ANTIGEN-POSITIVE FOR KIDD A ANTIGEN-POSITIVE FOR KIDD B ANTIGEN-POSITIVE FOR S ANTIGEN-NEGATIVE FOR s ANTIGEN

DI PHYSICIAN INSTRUCTIONS daratumumab treatment protocol

Add Spec. Test **Keyboard** Use reaction result grids

View of Daratumumab Patient BAD file information in BOP

213229

TEST,CANADA

Soc Sec #

ABO/Rh O-POS

RC Units Transf

Last Transf

AS Sum NEG

EXM Elig

Order Selection

Information (8)

Demographics

Linked /
Archived

Designated

History

Patient Demographics

Problems

DARA - PATIENT RECEIVED DARATUMUMAB

Antigens/Antibodies

NKEL - NEGATIVE FOR KELL ANTIGEN

NLTC - NEGATIVE FOR c ANTIGEN

NLTS - NEGATIVE FOR s ANTIGEN

PBGC - POSITIVE FOR C ANTIGEN

PBGE - POSITIVE FOR E ANTIGEN

PBGS - POSITIVE FOR S ANTIGEN

PFYA - POSITIVE FOR DUFFY A ANTIGEN

PFYB - POSITIVE FOR DUFFY B ANTIGEN

PJKA - POSITIVE FOR KIDD A ANTIGEN

PJKB - POSITIVE FOR KIDD B ANTIGEN

PLTE - POSITIVE FOR e ANTIGEN

Comments

Transfusion Attributes

Draft

Greensboro/

Reidsville

Procedure

TITLE: GUIDELINES FOR TRANSFUSING PATIENTS TAKING DARATUMUMAB (DARZALEX)

PRINCIPLE / PURPOSE: Daratumumab is used to treat some patients with multiple myeloma. This drug may interfere with routine blood bank serologic tests by directly binding to CD38 on RBCs. The binding of Daratumumab results in agglutination of erythrocytes which causes a positive indirect antiglobulin test, incompatible AHG crossmatch and panagglutinin in the antibody identification panel. The direct antiglobulin results are variable, may or may not be positive. Daratumumab induced agglutination can be seen up to 6 months after last dose.

SCOPE: This procedure applies to multiple myeloma patient receiving Daratumumab infusions.

COMPLEXITY LEVEL: High

SAFETY:

- The required personal protective equipment for this procedure:
 - Gloves
 - Disposable lab coat, worn closed
 - Safety shield
- Gloves and lab coats should be worn at all times during analysis of the samples.
- Samples must be opened and dispensed behind a safety shield.

PROCEDURE:

A. Blood bank sample is collected prior to administration of Daratumumab.

1. There is an order set in CHL requiring all patients starting Daratumumab to have a TYSCR and RBC phenotype ordered prior to infusion of the drug.
2. Enter problem code DARA (Patient received Daratumumab). Document date of infusion and facility given.
3. Perform Type and Screen
 - If the current antibody screen is negative and there is no history of clinically significant RBC antibodies, perform electronic crossmatch using phenotypically matched units.
 - If the current antibody screen is positive or there is a history of clinically significant RBC antibodies, perform IgG crossmatch
4. Perform a full RBC phenotype if patient has not been transfused in the past 3 months.
5. Give phenotypically matched blood if time permits. If urgent transfusion is needed, give units negative for C, c, E, e, and K depending on patient's phenotype.

B. Post Administration of Daratumumab with or without a transfusion history and RBC phenotype

1. Perform Type and Screen.
2. If antibody screen is positive, perform Antibody workup. If panreactivity is detected, inquire if Daratumumab was administered. If the patient was seen at another hospital and time permits, consult the blood bank at the other hospital. Inquire if RBC phenotype is available and if there is a history of alloantibodies. Document findings in patient's BAD file.

Note: The patient's historical phenotype information (not ABO and Rh) is acceptable from other institutions, provided documentation is faxed to us. Enter the phenotype using the appropriate blood bank comment codes directly into the Blood Bank Administrative Data (BAD) file or order and result a Patient Problem (PB) in BOP. Include a comment identifying the institution that performed the phenotype.

3. If Daratumumab was administered more than 30 days from the current type and screen, send a specimen to The Blood Connection for a full antibody workup.
4. Fill out a Blood Connection Reference Form. Request a full antibody workup and a full RBC phenotype if not previously in patient's BAD file.
5. When The Blood Connection completes testing and faxes a report, result the ABI as NSAR, Non-Specific Antibody Reactivity, and any other alloantibodies reported.
6. Add problem code, DARA (Patient received Daratumumab). Document date of infusion and facility given.
7. Enter problem code, GPB (Give phenotypically matched blood) if not already entered in the patient's BAD file.
8. Give phenotypically matched blood if time permits. If urgent transfusion is needed then give units negative for C, c, E, e, and K depending on patient's phenotype.
9. Perform AHG crossmatch using the method used for antibody screen and/ or panel.
10. If the crossmatch is incompatible in the IgG test phase, enter LICMP (Least Incompatible) for the crossmatch interpretation.
11. Contact the Medical Director and/or attending physician to get approval to transfuse least incompatible red cells.
12. Document the physician's approval as a blood bank comment (BBC). Add a VBO unit tag comment and document the approving physician's name.

PROCEDURAL NOTES:

N/A

REFERENCES:

Technical Manual, AABB, 19th Edition.

Standards for Blood Banks and Transfusion Services, AABB, 30th Edition

DRAFT