

## IMPORTANT INFORMATION

For the testing customers of Versiti Indiana, Inc. (Blood Center of Indiana)  
Donor Testing Laboratory



**TESTING  
SERVICES  
UPDATE**

### Testing Service Update (TSU) Table of Contents

TSU #	Date	Topic	Comments
#25-01	1/7/25	Change in Ortho Alternate Testing Provider	
email	10/25/24	#24-03 Follow-up – Confirmation of HCV II go-live 10/28/24	
email	8/12/24	#24-03 Follow-up – Clarification HCV II doesn't detect new virus	
#24-03	8/1/24	Change in Abbott Anti-HCV Testing	
#24-02	5/31/24	Change in Syphilis RPR Testing	
#24-01	4/25/24	Change in Donor Sample Testing Worksheet	<i>(Sent to impacted clients only)</i>
email	3/19/24	#23-02 Follow-up – Testing Again using Kit 72480	<i>(Sent to impacted clients only)</i>
email	3/5/24	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to CBB-NWPA only)</i>
email	2/16/24	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to SBMF only)</i>
email	1/23/24	#23-03 Follow-up – Immucor NEO-Iris go-live date eff. 2/5/24	
email	1/16/24	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to Milk Bank only)</i>
#23-03	12/27/23	Change in Antibody Screen and CMV Testing Platform	<i>New Immucor NEO-Iris</i>
email	12/27/23	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to Octapharma only)</i>
email	12/21/23	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to W.KY &amp; Revvity only)</i>
email	12/15/23	#23-02 Follow-up – Testing using Available Kit 72461	<i>(Sent to Blood Assurance, IU, Solvita, OSU, IDN, Univ.MI only)</i>
#23-02	12/15/23	Bio-Rad Geenius HIV Confirmatory Testing Delay	<i>(Sent to IDN &amp; Univ. of MI only)</i>
#23-02	11/26/23	Bio-Rad Geenius HIV Confirmatory Testing Delay	<i>(Sent to Versiti, Solvita, Blood Assurance, IU, OSU, HOX only)</i>
email	11/7/23	#23-01 Follow-up – “Nightshift” impacted clients transition to PK7400 (from PK7300) effective 12/4/23	<i>(Sent to impacted nightshift clients only)</i>
email	10/14/23	#23-01 Follow-up – “Dayshift” impacted clients transition to PK7400 (from PK7300) effective 11/14/23	<i>(Sent to impacted dayshift clients only)</i>
#23-01	9/22/23	Change in ABO/Rh and Syphilis Testing Platform	<i>New Beckman PK7400</i>
email	5/9/23	#22-03 Update – Captia Syphilis Testing Back In-house	
#22-03	12/21/22	Temporary Change in Captia Syphilis Testing	
#22-02	9/15/22	HBsAg Neutralization Interpretation Reporting Change	
email	6/24/22	#22-01 Follow-up – In-house BioRad Geenius™ HIV Confirmatory Testing Go-live	<i>Implement in-house 8/1/22</i>
email	1/25/22	#22-01 Follow-up – In-house BioRad Geenius™ HIV Confirmatory Testing delayed	<i>Not implementing 2/1/22</i>
#22-01	1/1/22	Change in Geenius™ HIV Confirmatory Testing	<i>Implement in-house 2/1/22</i>

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email	10/4/21	#21-01 Follow-up – “Nightshift” clients transition to Alinity (Prism retire) effective 11/15/21	<i>(Sent to nightshift clients only)</i>
email	8/23/21	#21-04 Follow-up – Roche Zika NAT test no longer available beginning 9/1/2021	
email	7/30/21	#21-01 Follow-up – “Nightshift” clients targeted to transition to Alinity (from Prism) effective 12/5/21	<i>(Sent to nightshift clients only)</i>
email	7/28/21	#21-01 Follow-up – “Dayshift” clients transition to Alinity (from Prism) effective 9/1/21	<i>(Sent to dayshift clients only)</i>
email	5/24/21	#21-02 Follow-up – Pooled Babesia implements 6/7/21	<i>(Sent to BAB clients only)</i>
email	5/14/21	#21-04 Follow-up – Clarification of 8/11 Zika end date	
#21-04	5/12/21	FDA Withdraws Guidance for ZIKV Testing	
email	5/10/21	#21-03 Follow-up – DTL sending HIV directly to CTS	
#21-03	4/28/21	Immediate Change in HIV Confirmatory Testing	
#21-02	3/2/21	Transition to Pooled Babesia Testing	<i>(Sent to BAB clients only)</i>
#21-01	2/18/21	Retiring Abbott Prism Testing Platform	<i>(Sent to all except Versiti WI &amp; IL, and SBMF)</i>
#20-07	12/23/20	Change in Handling ABO/Rh Historical Mismatches	
#20-06	12/15/20	Change in Ortho Testing Provider	
#20-05	11/23/20	Change in CMV Testing	
#20-04	10/20/20	Change in HIV Confirmatory Testing	
#20-03	9/30/20	New SARS-CoV-2 Antibody Test Offering	<i>(Sent to blood cntr clients)</i>
#20-02	7/31/20	Retiring Ortho Testing Platform	<i>(Sent to Versiti WI &amp; IL only)</i>
#20-01	7/8/20	Roche HBV NAT Re-Entry Singlet Testing	<i>(Sent to 10 bld cntr clients)</i>
#19-09	12/9/19	Licensure of Roche Cobas Babesia Test	
#19-08	11/1/19	Change in Anti-HCV Supplemental Testing	
#19-07	9/27/19	Update on South Bend Medical Foundation Change	<i>(Sent to all except SBMF)</i>
#19-06	9/26/19	Update on Retiring Grifols Testing Platform	
#19-05	8/22/19	Discontinuation of INNO-LIA HTLV Immunoblot Assay	<i>(Sent to select clients)</i>
#19-04	8/19/19	Changes for South Bend Medical Foundation Lab	
#19-03	7/12/19	Retiring Grifols Testing Platform	
#19-02	5/24/19	New Company Name Update	
#19-01	3/1/19	New Test Report for Captia Syphilis EIA Test	
#18-12	12/20/18	Back Order of MP HTLV Western Blot Reagent	
#18-11	11/29/18	Confirmatory Test Changes – Captia Syphilis EIA	
#18-10	11/28/18	Lab UPS Downtime	

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#18-09	11/21/18	Transition from Roche Cobas s201 to Roche Cobas 8800 Instruments	
#18-08	11/20/18	Confirmatory Test Changes - Chagas ESA & HTLV-WB	
#18-07	11/1/18	Second Notice of Invoicing and Remittance Changes	<i>(Sent to non-Versiti clients)</i>
#18-06	10/1/18	Notice of Legal Name Change and Invoicing/Remittance Changes	<i>(Sent to non-Versiti clients)</i>
#18-05	9/22/18	Transition to Pooled Zika Testing	<i>(Sent to Zika test clients)</i>
Memo	7/27/18	Change in Abbott Drain Time Error Test Provider	<i>(Sent to select clients)</i>
#18-04	7/9/18	FDA Approves Pooled Zika Testing	<i>(Sent to Zika test clients)</i>
#18-03	6/29/18	Supplemental Test Claim for Roche MPX 2.0 Test	<i>(Sent to all but BCW/HBC)</i>
#18-02	5/31/18	Change in HIV Confirmatory Test Provider	<i>(Sent to select clients)</i>
#18-01	4/30/18	New Courier Partner (change to MedSpeed)	<i>(Sent to select clients)</i>
#17-07	11/3/17	Roche Zika Licensed Assay Go-Live	<i>(Sent to select clients)</i>
#17-06	10/13/17	Roche Zika Licensure Update	<i>(Sent to select clients)</i>
#17-05	10/3/17	Roche Zika Assay Likely to License Soon	<i>(Sent to select clients)</i>
#17-04	9/27/17	Confirmatory Test Change - HIV-1 Western Blot	<i>(Sent to select clients)</i>
#17-03	3/10/17	WNV NAT Testing of HCT/P Donors	
#17-02	1/25/17	Implementation of Trinity Captia Syphilis Test (and Discontinuation of Immucor NEO TPHA Test)	<i>(Sent to select clients)</i>
#17-01	1/12/17	Surround 5.1 Update	
#16-12	12/9/16	Update on Immucor NEO TPHA Syphilis Test	
#16-11	10/25/16	Immucor NEO TPHA Syphilis Test Discontinuation	
#16-10	9/14/16	Implementation of Zika Testing	
#16-09	8/30/16	Planning for Zika Testing	
#16-08	5/17/16	Use of Roche NAT MPX 2.0 Assay for Re-Entry Testing	<i>Consult your FDA CSO</i>
TSU	4/4/16	Abbott Chagas ESA Confirmatory Test	<i>ARC price increase</i>
TSU	3/6/16	FDA Final Rule & New HTLV MP Blot 2.4 Test	<i>IBC to implement 5/23</i>
TSU	2/16/16	Syphilis Testing for NMDP Samples	<i>(Sent to select clients)</i>
TSU	2/8/16	Donor Re-Entry Using Roche MPX 2.0 (HIV-HBV-HCV all reported)	<i>(Sent to select clients)</i>
TSU	1/26/16	Roche MPX 2.0 Go-Live & AmpliSceen Discontinuation	
TSU	1/13/16	Lab Test Discontinuation (Labs, Inc. Scimedx FTA-ABS)	<i>(Sent to select clients)</i>
TSU	1/11/16	Versiti Testing Consolidation	<i>At IBC location</i>
TSU	12/18/15	Immucor NEO Implementation	<i>IBC to implement 1/19</i>
TSU	12/15/15	Roche MPX 2.0 Assay Implementation	<i>IBC to implement 1/26</i>

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TSU #	Date	Topic	Comments
TSU	12/10/15	Increased Syphilis IR and RR Rates	
TSU	12/4/15	Increased HIV IR and RR Rates	
TSU	11/4/15	Chagas ESA Confirmatory Testing	<i>ARC back-billing (Sent to select clients)</i>
TSU	10/30/15	New, Updated Roche MPX Assay	<i>MPX 2.0 soon available</i>
TSU	10/27/15	Serum Protein Electrophoresis Testing	<i>Change in lab provider (Sent to select clients)</i>
TSU	10/12/15	New CEO of IBC Announced	<i>Charlie Miraglia, MD</i>
TSU	9/16/15	SWI Unavailable (Sunday 9/20/15)	
TSU	7/9/15	T.cruzi (Chagas) Reagent Lot Update	<i>RR rate resolution</i>
TSU	6/23/15	Syphilis Testing	<i>IBC reflex to NEO TPHA</i>
TSU	5/11/15	Holiday Testing Hours for Memorial Day Weekend	
MEMO	5/1/15	Add-On Testing Form	<i>New Form TL100-02.5</i>
TSU	4/27/15	T.cruzi (Chagas) Reagent Lot Update	<i>Increased RR rate</i>
TSU	4/21/15	CTTM Name Change to Versiti	
TSU	12/29/14	New HTLV Confirmatory Test	<i>MP Blot 2.4 licensed</i>
TSU	12/22/14	Christmas & New Year's Day Testing Schedule	
TSU	12/21/14	Introduction of Updated Form	<i>Revised TL100-04.2</i>
TSU	12/17/14	Clarification of NAT Test Sample Requirement	
TSU	12/1/14	Chagas Confirmatory/Supplemental Testing	<i>Test options available</i>
TSU	11/24/14	Change in HIV-2 Confirmatory Testing Lab	<i>Change in lab provider</i>
TSU	11/17/14	IBC Joins Alliance of Blood Centers (CTTM)	
TSU	11/12/14	Thanksgiving Holiday Testing Schedule	
TSU	10/13/14	CLIA Laboratory Director Update	<i>Now Dr Cruz</i>
MEMO	9/26/14	Chagas Reflex Testing	<i>RIPA test discontinuing</i>
MEMO	8/6/14	Labor Day Testing Schedule (All Clients)	
MEMO	8/6/14	Labor Day Testing Schedule (MiBC only)	<i>(Sent to select clients)</i>
Survey	7/21/14	Customer Resource Manual Questionnaire	
TSU	7/18/14	Elimination of BacT Bottle Qualification	<i>(Sent to select clients)</i>
MEMO	7/8/14	RPR Titer Testing	<i>Bringing test in-house</i>
MEMO	6/26/14	HBV NAT Donor Re-Entry Testing	<i>Bringing test in-house</i>
TSU	6/23/14	Holiday Testing Hours for Independence Day	
MEMO	5/8/14	CMV Discriminatory Testing	<i>Discontinuing in-house</i>
MEMO	2/17/14	Change to Requisition TL110-04.2	<i>Effective immediately</i>

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MEMO	5/14/13	Memorial Day, July 4 <sup>th</sup> and Labor Day Holiday Lab Schedule	
MEMO	3/13/13	Novartis Chiron HCV RIBA 3.0 SIA Test Discontinued	<i>Previously established use of 2<sup>nd</sup>/Ortho screen test</i>
MEMO	3/11/13	Eliminate (duplicate) Hardcopy Mailing of Test Results	<i>4/1/13 effective date</i>
MEMO	2/11/13	Eliminate (duplicate) Hardcopy Mailing of Test Results	<i>Proposed change seeks client input</i>
MEMO	1/11/13	Move to 7-day-a-week Testing (adding Sunday testing day)	<i>2/3/12 effective date</i>
MEMO	10/17/12	HCV RIBA 3.0 Test Unavailable Update	<i>IBC samples sent for 2<sup>nd</sup>/Ortho test pending Variance approval</i>
MEMO	10/16/12	HCV RIBA 3.0 Test Unavailable Update	<i>Each client must submit Variance</i>
MEMO	10/10/12	HCV RIBA 3.0 Test Unavailable (now archiving samples)	<i>Submit FDA Variance for use of 2<sup>nd</sup>/Ortho test</i>
MEMO	9/26/12	Novartis Chiron HCV RIBA 3.0 SIA Test Unavailable Mid-Oct	<i>Propose use of 2<sup>nd</sup>/Ortho screen test</i>
MEMO	9/12/12	Limited Availability of Novartis Chiron HCV RIBA 3.0 SIA Test	<i>SBMF send to LifeSource eff. 9/13</i>
MEMO	9/5/12	Move from Manual Nagoette Chamber to Flow Cytometry WBC	<i>Effective immediately</i>
MEMO	7/27/12	Limited Availability of Novartis Chiron HCV RIBA 3.0 SIA Test	<i>SBMF move to test only weekly</i>
MEMO	6/21/12	July 4 <sup>th</sup> and Labor Day Holiday Lab Schedule	
MEMO	2/20/12	Use of HBV NAT Test in Determining Neutralization Reflex Testing of HBsAg+ Samples	
MEMO	4/29/11	Update on Elevated Chagas Repeat Reactive Rate	<i>w/in PI; Abbott work on conf. test</i>
MEMO	4/26/11	Phoenix Biotech Trep-Sure, ASI RPR Card & Captia CMV IgG/IgM Tests Performed In-House at IBC	<i>5/2/11 effective date</i>
MEMO	4/25/11	Elevated Chagas Repeat Reactive Rate	<i>Since move to Abbott Prism</i>
MEMO	4/15/11	Ortho FDA Submission of New Ortho HCV RIBA Test	<i>SBMF use current test thru 5/6/11</i>
MEMO	4/12/11	Questionable Future Availability of Ortho HCV RIBA Test	
MEMO	4/12/11	Move from Chiron to Roche MPX/WNV NAT Testing Platform	<i>6/2/11 effective date</i>
MEMO	4/5/11	PK-TP Reagent Switch from ASI Inc. to Olympus Reagent	<i>4/15/11 effective date</i>
MEMO	2/16/11	Lean Trial Changes to Lot Release <i>(release by TL LR eff.2/28/11)</i>	<i>With QA LR performed after</i>
MEMO	2/10/11	Resolution to Abbott Prism Increased Error Codes	
MEMO	1/31/11	Move from Ortho to Abbott Prism Chagas Testing Platform	<i>2/14/11 effective date</i>
MEMO	1/7/11	Reminder of Mover from Abbott Aeroset to Roche Cobas c501	
MEMO	10/20/10	Move from Abbott Aeroset to Roche c501 for Chol/Trig Tests	<i>10/5/10 effective date</i>
MEMO	9/10/10	Abbott Prism HIV-O Reagent Recall (IBC is NOT impacted)	<i>IBC did not receive affected lot</i>
MEMO	6/16/10	July 4 <sup>th</sup> and Labor Day Holiday Lab Schedule	
MEMO	5/17/10	Memorial Holiday Lab Schedule	