

Resulting and Archiving Bordetella Results

PURPOSE

This procedure provides instructions for resulting and filing *Bordetella* results in LIS.

POLICY STATEMENT

Alert value: Call patient's caregiver with positive results for *B. pertussis* and *B. parapertussis*. Document the name of
person called, date and time; refer to the <u>Laboratory Services</u> web page

ABBREVIATIONS

- ASR: analyte-specific reagent
- BICCT: Bordetella internal control Ct value
- BORD: Bordetella
- BORDP: Bordetella PCR
- BPCT: B. pertussis Ct value
- BPPCT: B. parapertussis Ct value
- BPDNA: B. pertussis interpretation
- BPPDN: B. parapertussis interpretation
- Ct: crossing threshold

- FDA: US Food and Drug Administration
- IC: internal control
- LIS: laboratory information system
- NA: not applicable
- PCR: polymerase chain reaction
- SAS: Specimen description
- STYP: specimen type code
- WO: worksheet

DOCUMENTATION/RECORDS

- BORDP Segment Report
- LIS Incomplete worksheet, SmarTerm Function WO, options #1

PROCEDURE A: Follow the activities below for reporting and archiving patient results **Reporting Patient Results**

Activity	Step	Action								
Export results	1	Export patient test results from the <i>Simplexa</i> instrument to LIS; see <u>MB 6.05</u> procedure H								
	2	Reporting activities are performed in the Molecular Office								
Computer	3	Enter resul	Enter results in Sunquest Result Entry							
Entry		S	Step	Prompt	Action/Entry					
Molecular			а		Click on the Sunquest icon to log on					
S			b	User	CExxxxx					
			С	Password	XXXXXXX					
			d	Location	R					
			e		Click OK					
	4	Select Result	Select Result Entry from Menu options							
SIM	5	Figure 1: Int dro	terfac op do	e Configurati wn box	ion: Select SIM from Resulting mode (0)					
	6	located in the lower left corner								



Activity	Step	Action							
SIM	7	If the page says "Waiting for cups", the results were not successfully transmitted or the results page was accessed too quickly before the transmission was completed							
STYP code or missing code	8	STYP codes: This specimen was grayed out and not checked for release because there was a problem with the specimen type code.							
Destau		Figure 2: Review messages located on the top and results							
Review Messages		Specimen messages Failed cup criteria Test messages INVALID RESULT A calculation is defined for this test and modification is not							
Result Entry		allowed. atus Specimen Method Cup Release BPCT BHCT BICCT BPDNA BPDNA Display:							
		T60651 SIM2 4 30.5 0.0 27.5 POS-ASRS NEG-ASRS Failure T61141 SIM2 5 0.0 27.5 POS-ASRS NEG-ASRS Verify							
		T81296 SIM2 7 I 29.3 0.0 27.5 POS-ASRS NEG-ASRS Techn							
	9	Solution: STYP codes can be corrected in Sunquest Order Entry or SmarTerm MEM							
		Step Prompt Action/Entry							
SmarTerm		a Fixing specimen type codes in SmarTerm							
~		c WORKSHEET NA : Do not enter for manual entry without calculations							
		d TEST BORDP							
		e ACCEPT A							
		fACC. NO.Add missing code: F66931•Replacing STYP code: M-F66931 (M for modify)							
		g SAS Replace existing code or enter missing code NP							
Duplicate results	10	Figure 3: If a run is exported more than once, uncheck the duplicate results and release the checked results							
		Specimen messages Preprocessing passed							
THE .		Apply Defaults Specimen appears in multiple cups on the instrument, i.e. cups 1							
Result Entry		Status Specimen Method Cur Release BPCT BPPCT BICCT BPDNA BPPDN							
		F66931 SIM3 1 📝 0.0 0.0 28.9 NEG-L20-ASRS-L20 NEG-L2							
		F66931 SIM3 2 0.0 0.0 28.9 NEG-L20-ASRS-L20 NEG-L2							
	11								
	11	Click button located on the lower left corner							
	12	Duplicate Specimens X							
		You have selected to release one or more specimens with results in multiple cups on the instrument.							
		Accession Cups							
		Figure 4' Duplicate Specimens							
		Do you want to release the selected cups with duplicate specimens2							
		Do not release duplicates Cancel							
	13	Click Release All							



Activity	Step	Action					
	14	Figure 5: Verify Release to Lab; click Accept					
		If Then					
No Problems	15	 Specimen box reads <i>Preprocessing passed</i> with no further messages Test box has no messages Sample results are acceptable Click Save and then Accept (Fig. 5) 					
	16	 Record Control results from BORD Segment Report on BORDP worksheet Record Ct values in BPCT, BPPCT and BICCT columns Interpretation: Valid or Invalid 					
Archive	17	Staple worksheet containing specimen identifiers used during testing and BORD Segment Report together					
	18	Place report in the Bordetella result log book located in the Molecular office					

PROCEDURE B: Follow the activities below for documenting phoned results **Phoned Results, GUI interface**

Activity	Step	Action							
Alert Values	1	Positive <i>B. pertussis</i> and <i>B. parapertussis</i> are Alert Values that require the result to be called to the patient's caregiver and documented in LIS							
Result Entry Enter free text	2	Enter phoned results in Result Entry – [SIM] Figure 6: Click on the Interpretation box to expand the result	Result NEG L20 ASRS L20 ;called to Ruth H, RN @1230 on 7/22/16						
	3	At the blinking cursor, type a semicolon in the box to indicate Free Text mode (Fig. 6)							
	4	Type the first name and last initial of the person called and date and time (Fig. 6)							
	5	Check carefully for entry errors							
	6	Close interpretation box							
Review	7	Figure 7: Hover over the result with the mouse to review the full description HEG-LOD-ASRS-L2D-Colled to R Verify HEG-LOD-ASRS-L2D-Colled to R Verify NEGATIVEAnalyte Specific Reagent: This test was developed and its performance determined by Children's Hospitals and Clinics of MN. It has not been cleared or approved by the FDA;Called to Ruth H, RN 01220 on 7/22/16							
	8	Click Save and then Accept on the Verify Release screen (Fig. 5) to file results in LIS							



PROCEDURE C: Follow the activities below for result manual entry in function MEM **Manual entry in function MEM**

Activity	Step	Action									
	1	If a specime MEM	If a specimen has failed the cup criteria (Fig. 2) and results do not display, enter results in function MEM								
Manual	2	Worksheet I	BORDP is required for result interpretive calculations								
Entry	_		Step	Prompt	Action/Entry						
			а		Manual entry in SmarTerm						
			b	FUNCTION	MEM						
SmarTerm			С	WORKSHEET	BORDP [required for worksheet calculations]						
			d	TEST	BORDP						
			е	ACCEPT	Α						
			f	ACC. NO.	F66931						
			g	SAS	NP						
								h	BPCT	39.1	
					i	BPPCT	0				
			j	BICCT	29.7						
			k	BPDNA	NEG-ASRSG [automatic worksheet calculation]						
			L	BPPDN	NEG-ASRSG [automatic worksheet calculation]						
			m	ACCEPT	A						

PROCEDURE D: Follow the activities below for documenting phoned results manually after results have been released in Sunquest *Result Entry* – [SIM]

Phoned Results, Manual entry in function MEM

Activity	Step	Action								
	1	If unable to reach patient's caregiver regarding an Alert Value, release positive results so they are available in Cerner								
Alert Values	2	Once patie	ce patient's caregiver has been contacted, document phoned results manually in LIS function							
			Step	Prompt	Action/Entry					
Manual			а		Manual entry in SmarTerm					
Entry			b	FUNCTION	MEM					
			С	WORKSHEET	NA : Do not enter for manual entry without calculations					
с т			d	TEST	BORDP					
Smarlerm			е	ACCEPT	Α					
			f	ACC. NO.	Modify result: M – F66931					
			g	SAS	NW					
			h	BPCT	28 [interface results will automatically populate]					
			i	BPPCT	0					
			j	BICCT	27					
			k	BPDNA	POS-L20-BPHP-ASRS-L20					
			Ι		Click Phoned Result					
			m	NAME	Enter name, last initial and credential, i.e., RN or MD					
			n		Click OK, date and time stamp will default					
			0	BPPDN	NEG-L20-ASRS-L20					
			р	ACCEPT	Α					



PROCEDURE E: Follow the activities below for result manual entry in SmarTerm Function MEM Inhibitory / Abnormal Results (Table 1)

Activity	Step	Action			
	1	Entering resu	ılt cod	es manually;	; refer to table 1
Manual		St	ep P	rompt	Action/Entry
Entry		а			Manual entry in SmarTerm
hnormal		b	F	UNCTION	MEM
results		С	V	VORKSHEET	NA : Do not enter for manual entry without calculations
Counto		d	Т	EST	BORDP
SmarTerm		e	A	CCEPT	A
		f	A	CC. NO.	F66931
		g	S	AS	NW
		h	В	PCT	0 [enter Ct values from BORD segment report]
		i	В	PPCT	0
		j	В	SICCT	0
		k	В	PDNA	UNR-ASRSG
		1			Click Phoned Result
		m	N	IAME	Enter name, last initial and credential, i.e., RN or MD
		n			Click OK, date and time stamp will default
		0	В	PPDN	UNR-ASRSG
		р			Click Phoned Result
		q	Ν	IAME	Enter name, last initial and credential, i.e., RN
		r	A	CCEPT	Α

Table 1: Sunquest Result Codes

Result	Sunquest code	Interpretation
Positive B. pertussis	POS-BPHP-ASRSG (MEM) Interface POS-L20-BPHP-ASRS-L20	 Positive A positive result does not distinguish between <i>B. pertussis</i> and <i>B. holmseii</i> Analyte Specific Reagent: This test was developed and its performance determined by Children's Hospitals and Clinics of MN. It has not been cleared or approved by the FDA
Positive B. parapertussis	POS -ASRSG (MEM) Interface POS-L20-BPHP-ASRS-L20	 Positive Analyte Specific Reagent: This test was developed and its performance determined by Children's Hospitals and Clinics of MN. It has not been cleared or approved by the FDA
Negative	NEG-ASRSG (MEM) Interface NEG-L20-ASRS-L20	 Negative Analyte Specific Reagent: This test was developed and its performance determined by Children's Hospitals and Clinics of MN. It has not been cleared or approved by the FDA



Result	Sunquest code	Interpretation
Unresolved Results	UNR - ASRSG Function: MEM Worksheet: NA Test: BORDP	 Unresolved: This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated. ASR / FDA statement Phoned Result [free text name]
Amplification curve abnormal IC not inhibited	EQ – ASRSG Function MEM Worksheet: NA Test: BORDP	 Equivocal result, suggest repeat specimen ASR / FDA statement Phoned Result Phoned Result [free text name]
Corrected report	Function MEM Worksheet: BORDP Test: BORDP	 Modify results in function MEM by typing M followed by a hyphen: M-T54966 Enter correct numerical result in BPCT, BICCT or BPPCT field(s). Computer will interpret and automatically put in a correction statement Phoned Result [free text name]

PROCEDURE F: Follow the activities below for modifying results in SmarTerm Function MEM **Corrected Report**

Activity	Step	Action				
	1	Corrected	l report	t: Changing data	a and interpretation	
Manual			Step	Prompt	Action/Entry	
Lifery			а		Manual entry in SmarTerm	
Modifying			b	FUNCTION	MEM	
results			С	WORKSHEET	BORDP [necessary for interpretive calculations]	
Create in The same			d	TEST	BORDP	
Smarterm			е	ACCEPT	A	
			f	ACC. NO.	M – F66931	
			g	SAS	NW	
			h	врст	0 – enter correct Ct value below previous value34 Correction statement will automatically default	
			i	BPPCT	0	
			j	BICCT	0	
			k	BPDNA	NEG-L20-ASRS-L20 POS-ASRSG Corrected on 8/16 AT 1432: PREVIOUSLY REPORTED AS NEGATIVE [automatic correction statement]	
			I		Click Phoned Result	
			m	NAME	Enter name, last initial and credential, i.e., RN, MD	
			n		Click OK, date and time stamp will default	
			0	BPPDN	NEG-L20-ASRS-L20	
			р	ACCEPT	Α	



REFERENCES

- 1. Laboratory for Windows User's Guide, UD-1599/00-12-GL, Sunquest Information Systems
- 2. CAP Microbiology Checklist, Section Department: Molecular Diagnostics, MIC.64988, 04.21.2014, College of American pathologists, 325 Waukegan Rd, Northfield, IL 60093

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	Pat Ackerman	07.20.16	Initial Version