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Solana®

Bordetella Complete ASSAY

FOR USE WITH SOLANA
For the qualitative detection of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens.

For *in vitro* diagnostic use.

℞ ONLY

A symbols glossary can be found on quidel.com/glossary.

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INTENDED USE

The Solana Bordetella Complete Assay is an *in vitro* diagnostic test for the qualitative detection of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* and *Bordetella parapertussis*.

The Solana Bordetella Complete Assay is an HDA-based duplex assay that targets the IS481 and IS1001 sequence of *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) genomes, respectively. The IS*481* sequence may also be found in strains of other organisms (i.e., *B. holmesii* and *B. bronchiseptica*). The IS*1001* sequence may also be found in strains of other organisms (i.e., *B. bronchiseptica*). *B. holmesii* infection may cause clinical illness similar to *B. pertussis,* and mixed outbreaks involving both B. *pertussis* and *B. holmesii* infection have been reported. Additional testing should be performed if necessary to differentiate *B. holmesii and B. pertussis. B. bronchiseptica* is a rare cause of infection in humans. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

Negative results for the Solana Bordetella Complete Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infection with other respiratory pathogens. Results from the Solana Bordetella Complete Assay should be used in conjunction with information obtained during the patient's clinical evaluation as an aid in diagnosis of *Bordetella pertussis* and or *B. parapertussis* infection and should not be used as the sole basis for treatment or other patient management decisions.

PRINCIPLE OF THE TEST

The Solana Bordetella Complete Assay amplifies, detects and differentiates DNA of *Bordetella pertussis* and *Bordetella parapertussis* from nasopharyngeal swabs

The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequences specific to *B. pertussis* and *B. parapertussis* using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probes.

A patient nasopharyngeal swab specimen in transport media is transferred to a Process Buffer Tube, subjected to heat treatment at 95 °C for 5 minutes and mixed. The processed sample is transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of *B. pertussis* and *B. parapertussis*-specific target sequences. In Solana, the target sequences are amplified by *B. pertussis* and *B. parapertussis* specific primers and detected by *B. pertussis* and *B. parapertussis*-specific fluorescence probes, respectively. A process control (PRC) is included in the Process Buffer Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by specific primers and detected by a PRC specific fluorescence probe.

The two target probes and PRC probe are labeled with a quencher on one end and a fluorophore on the other end. In addition, the two target probes and PRC probe have one or more bases that are comprised of ribonucleic acid. Upon annealing to *B. pertussis* and *B. parapertussis* or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana then reports the test results to the user on its display screen, and it can print out the results via an attached printer.

MATERIALS PROVIDED

Cat. #M308
48 Tests per Kit

Component	Quantity	Storage
Process Buffer	48 tubes/kit, 1.45 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

- External controls for *B. pertussis* and *B. parapertussis* (e.g. Quidel Molecular Bordetella Control Set, Cat. # M117 which contains positive and negative controls, serves as an external processing control)
- Scissors
- Vortex Mixer
- Solana workflow tray and transfer rack
- Solana instrument
- Heat block capable of 95° ± 2°C temperature

WARNINGS AND PRECAUTIONS

Local, state, and federal regulations for notification of reportable diseases are continually updated and include a number of organisms for surveillance and outbreak investigations. Laboratories are responsible for following their state and/or local regulations and should consult their local and/or state public health laboratories for isolate and/or clinical sample submission guidelines.

- Refer to the Solana User Manual for further information regarding instrument installation and operation.
- All reagents are for *in vitro* diagnostic use only.
- Only use the protocol described in this package insert. Deviations from the protocol may give erroneous results.
- Treat all specimen/samples as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- All tubes should be capped tightly prior to vortexing.
- Proper sample collection, storage and transport are essential for correct results.
- Store assay reagents as indicated on their individual labels.
- Reagents are not interchangeable between lots.
- Never pool reagents from different tubes even if they are from the same lot.
- Do not use the reagents after their expiration date.
- Do not interchange caps among reagents as contamination may occur and compromise test results.
- Only open the tubes when adding aliquots into tubes or removing aliquots from tubes. Keep the tubes closed at any other time to avoid contamination.
- To avoid contamination of the environment with amplicons, do not open the reaction tubes post-amplification.
- Avoid microbial and deoxyribonuclease (DNase) contamination of reagents when removing aliquots from tubes. The use of sterile DNase-free disposable filter-blocked or positive displacement pipettor tips is recommended.
- Use a new pipettor tip for each specimen or reagents.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.

- For accurate results, pipette carefully using only calibrated equipment. Use of inaccurate volumes may give erroneous results.
- Maintenance and decontamination of workspace and equipment should follow and be performed according to established laboratory protocols and schedules. Testing should be performed in an area with adequate ventilation.
- Use micropipettes with an aerosol barrier or positive displacement tips for all procedures.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

Store the Assay Kit at 2° to 8°C until the expiration date listed on the outer kit box.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Specimen Type: Nasopharyngeal swabs (flocked swabs or rayon swabs with aluminum shaft).

Nasopharyngeal swabs used for the validation of the Solana Bordetella Complete Assay were obtained using standard techniques from patients suspected of having respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*.

Specimens can be stored at 2°C to 8°C for up to 97 hours, up to 49 hours at 25°C before processing, or up to 5 months at ≤ −70°C.

Swabs can be eluted in either saline (0.85%), Tris EDTA, Molecular Grade Water, Amies liquid media (i.e. E-Swab™), or UTM™, M4®, M4RT®, or M6® viral transport media.

A series of analytical studies were performed evaluating a number of routinely used transport media at a volume of 3 mL: M4®, M4RT®, and M5®. Molecular Grade Water, Saline (0.9%), Tris-EDTA, Amies transport media (Eswab) were also evaluated.

No significant difference in assay performance was seen between the five different types of viral transport media, saline (0.85%), Tris EDTA, Molecular Grade Water, or Amies.

NOTE: The M4®, M4RT®, and M5® were only validated analytically.

TEST PROCEDURE

1. Turn on Solana by pressing the power button and wait until it completes self-testing.
   Note: Do not open the lid during the self-testing.
2. Place the required number of Process Buffer Tubes in the Workflow tray. Mark the Process Buffer Tubes on the cap and/or side of the tube.
   Note: One (1) Process Buffer Tube is required for each specimen or control to be tested.
   Note: A maximum of 12 tests can be performed per test run in a single Solana instrument.
3. Remove the required number of Reaction Tubes from the protective pouch and place in the Workflow tray. Mark the Reaction Tubes on the cap. Remove the excess air and reseal the pouch.
4. Mix the specimen by vortexing the tubes for 5 seconds.
5. Remove 50 µL of the mixed specimen or External control and add to labeled Process Buffer Tubes and then vortex the Tubes for 5 seconds.
6. Heat the Process Buffer Tubes at 95°C for 5 minutes and then vortex the Tubes for 5 seconds.
   Note: Begin 5-minute lysis procedure when the heat block measures 95°C ± 2°C. The timer must be stopped if the temperature falls out of range at any time during the 5-minute period and cannot be restarted until the heat block returns to 95°C ± 2°C.

Note: The processed specimen is stable for up to 97-hours when stored at 2°C to 8°C or up to 49-hours when stored at 25°C.

7. Rehydrate the marked Reaction Tubes with 50 µL of each Process Buffer by Vigorously pipetting up and down 5 times. The solution should be clear, free of solid material.
8. Using the Solana Transfer Rack to hold Reaction Tubes at eye-level, visually inspect each Reaction Tube to ensure pellet rehydration.
9. Open the lid and place the Reaction Tubes in Solana via the Transfer Rack. Close the lid**.**
   Note: Be sure that all tubes are in tight contact with heat block.
10. Enter User ID, press ↵ (ENTER) and enter Password and press ↵ (ENTER).
11. Select "NEW TEST". If Solana displays a different screen, go to the home screen.
12. Select the tube positions to use.
13. Scan the assay barcode or manually enter Lot ID/Exp Date, then select "Bordetella" from the Select Test drop-down menu and press "►".
14. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (optional; see 2nd Note in next step).
15. Press "Start" to initiate the Solana Bordetella Complete Assay and confirm that the tubes have been inserted into the instrument. Solana will display both the progress and the count-down to assay completion, and the test results will be displayed on the screen in approximately 50 minutes.
    Note: To avoid laboratory contamination, once the tube has been closed and the amplification reaction started, **DO NOT** open the Reaction Tube.
    Note: While the test is running, sample ID can be entered or edited by pressing the pencil icon.
16. After the run is completed the results can be printed by selecting the print button. The results may also be viewed and printed by going to Home and then selecting Review Results.
18. To determine if sample is positive for *B. pertussis* or *B. parapertussis* press the tube sample number. Separate results for the *B. pertussis* and *B. parapertussis* channels will be displayed.

INTERPRETATION OF RESULTS

All Samples Results Screen		
Samples	Assay Result	Interpretation
Patient specimen	POSITIVE	*B. pertussis* and/or *B. parapertussis* DNA detected
	NEGATIVE	No *B. pertussis* or *B. parapertussis* DNA detected/PRC detected
	INVALID	No *B. pertussis* or *B. parapertussis* DNA and No PRC detected; for invalid test results, re-process another aliquot of the same sample or obtain a new sample and re-test.

Single Sample Results Screen		
Samples	Assay Result	Interpretation
Patient specimen	*B. pertussis* DNA POSITIVE	*B. pertussis* DNA detected
	B. parapertussis DNA POSITIVE	*B. parapertussis* DNA detected
	B. pertussis NEGATIVE	No *B. pertussis* DNA detected/PRC detected
	B. parapertussis NEGATIVE	No *B. parapertussis* DNA detected/PRC detected
	B. pertussis INVALID / *B. parapertussis* INVALID	No *B. pertussis* or *B. parapertussis* DNA and No PRC detected; for invalid test results, re-process another aliquot of the same sample or obtain a new sample and re-test.

QUALITY CONTROL

The Solana Bordetella Complete Assay incorporates several controls to monitor assay performance.

- The process control is used to monitor sample processing, to detect HDA inhibitory specimens, to confirm the integrity of assay reagents and the operation of the Solana instrument. The process control is included in the Process Buffer tube.

- Quidel Molecular Bordetella external positive controls may be treated as a patient specimen. Identify the Process Buffer tube as the positive control and proceed with processing as described above in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.
- Quidel Molecular Bordetella external negative controls may be treated as a patient specimen. Identify the Process Buffer tube as the negative control and proceed with processing as described above in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by BP or BPP DNA or amplicon.

It is recommended that the reactivity of each new lot and each new shipment of the Solana Bordetella Complete Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana Bordetella Complete Assay should not be used in patient testing if the external controls do not produce the correct results.

LIMITATIONS

- The Solana Bordetella Complete Assay should only be used on the Solana Instrument by trained personnel.
- The Solana Bordetella Complete Assay does not distinguish between viable and non-viable organisms and should not be used to assess therapeutic success or failure because BP and BPP DNA may persist following antimicrobial treatment.
- The IS*481* sequence used in the Solana Bordetella Complete Assay can also be found in strains of other organisms (i.e., *B. holmesii* and *B. bronchiseptica*). The IS*1001* sequence may also be found in strains of other organisms (i.e., *B. bronchiseptica*). *B. holmesii* infection may cause clinical illness similar to *B. pertussis,* and mixed outbreaks involving both *B. pertussis and B. holmesii* infection have been reported. Additional testing should be performed if necessary to differentiate *B. holmesii and B. pertussis. B. bronchiseptica* is a rare cause of infection in humans. When clinical factors suggest that *B. pertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.
- As with all molecular based diagnostic tests, (A) False-negative results may occur from the presence of inhibitors, technical error, sample mix-up or low numbers of organisms in the clinical specimen; (B) False-positive results may occur from the presence of cross-contamination by target organisms, their nucleic acids or amplified product, and from non-specific amplification signals.
- Respiratory infections can be caused by Bordetella pertussis as well as other pathogens. Positive results do not preclude coinfection with other respiratory pathogens. False-negative Bordetella pertussis results are more likely if patients are tested later in the disease course (more than two weeks after symptom onset), due to declining concentrations of Bordetella DNA. False-negative results may also be increased in patients treated with antibiotic therapy.
- Environmental contamination of an exam room from a prior patient or a recent pertussis vaccination administration may result in false-positive test results.
- Results from this test must be correlated with the clinical history, epidemiological data, and any other data available to the clinician.
- This test has not been evaluated for specimens other than nasopharyngeal swab specimens, for immunocompromised individuals or from patients not suspected of infection with *Bordetella pertussis* and *Bordetella parapertussis*.

EXPECTED VALUES

The expected values of the Solana Bordetella Complete Assay were established during a prospective study conducted between October 2017 to January 2018. Seven hundred forty-one (741) fresh nasopharyngeal swab specimens, obtained from female and male patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis*, were collected and transported to four (4) laboratories for testing with the Solana Bordetella Complete Assay. A single specimen was collected per patient.

The prevalence of *Bordetella pertussis* and *Bordetella parapertussis* detected with the Solana Bordetella Complete Assay has been calculated for the combined sites based on the age of the patient. Four (4) specimens (0.5%) were invalid (in both the initial and repeat test) and have been removed from the Expected Values table. The table below presents the data for the remaining seven hundred thirty-seven (737) specimens.

Combined Fresh Specimen Study Expected Values (N=737)					
		Bordetella pertussis		***Bordetella parapertussis***	
Age	Total #	Total Positive	Prevalence	Total Positive	Prevalence
≤ 2 years	241*	3	1.2%	4	1.7%
3 to 12 years	210**	4	1.9%	6	2.9%
13 to 21 years	102	6	5.9%	0	0.0%
≥ 22 years	184	1	0.5%	0	0.0%

* Two (2) specimens were invalid

** Two (2) specimens were invalid

CLINICAL PERFORMANCE

A multi-center study was performed to evaluate the Solana Bordetella Complete Assay using nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis*. The study was performed during the Winter of 2017 to 2018 (October, 2017 to January, 2018) at one (1) internal and four (4) external sites in the United States. The study used seven hundred forty-one (741) fresh specimens at four (4) sites, and two hundred thirty-three (233) frozen archival specimens at four (4) sites.

Clinical performance was based on comparison of the Solana Bordetella Complete Assay results to those obtained by a Composite Reference Method that included two (2) manufacturer validated, IS481-targeted PCR assays and bi-directional sequencing. The PCR assay protocols included 37 amplification cycles.

Combined Fresh Specimen Data

Seven hundred forty-one (741) fresh nasopharyngeal swab specimens, obtained from female and male patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis,* were prospectively collected and transported to each laboratory for testing with the Solana Bordetella Complete Assay. Four (4) specimens (0.5%) were invalid (in both the initial and repeat test) and have been removed from further analysis. The tables below present the data for the remaining seven hundred thirty-seven (737) specimens.

Prospective Study: Combined Site Fresh Specimens – Composite Reference Method versus Solana Bordetella Complete Assay for *B. pertussis*			
	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	12	2	14
Negative	0	723	723
Total	12	725	737
			95% CI
Positive Percent Agreement	12/12	100%	75.7% to 100%
Negative Percent Agreement	723/725	99.7%	99.0% to 99.9%

Prospective Study: Combined Site Fresh Specimens – Composite Reference Method versus Solana Bordetella Complete Assay for *B. parapertussis*			
	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	10	0	10
Negative	0	727	727
Total	10	727	737
			95% CI
Positive Percent Agreement	10/10	100%	72.2% to 100%
Negative Percent Agreement	727/727	100%	99.5% to 100%

Combined Frozen Archival Specimen Data

Two hundred thirty-three (233) selected frozen archival nasopharyngeal swab specimens were obtained from female and male patients previously tested for the presence of *Bordetella pertussis* or *Bordetella parapertussis.* The specimens were tested with the Solana Bordetella Complete Assay and the Composite Reference Method. The tables below present the data for the specimens.

Combined Site Archival Specimens – Composite Reference Method versus Solana Bordetella Complete Assay for *B. pertussis*			
	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	155	6	161
Negative	3	69	72
Total	158	75	233
			95% CI
Positive Percent Agreement	155/158	98.1%	94.6% to 99.4%
Negative Percent Agreement	69/75	92.0%	83.6% to 96.3%

Combined Site Archival Specimens – Composite Reference Method versus Solana Bordetella Complete Assay for *B. parapertussis*			
	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	12	3	15
Negative	0	218	218
Total	12	221	233
			95% CI
Positive Percent Agreement	12/12	100%	75.7% to 100%
Negative Percent Agreement	218/221	98.6%	96.1% to 99.5%

Contrived *Bordetella parapertussis* Panel Testing

A study was performed to demonstrate the sensitivity of Solana Bordetella Complete Assay using three (3) levels of *Bordetella parapertussis* (BPP) (two (2) strains) in negative specimen matrix at two (2) testing locations. Each individual specimen was prepared using a unique negative NP specimen matrix.

Contrived Panel Result Summary			
Panel Members	**# of Samples**	**BPP Concentrations**	**Results**
Negative	20	0	Negative: 100% (20/20)
BPP Low Positive	 10 10	**2.5X LOD** BPP A747 (1.2 x10^4 CFU/mL) BPP E838 (1.4 x10^4 CFU/mL)	 100% (10/10) 100% (10/10)
BPP Moderate Positive	 6 6	**10X LOD** BPP A747 (4.6 x10^4 CFU/mL) BPP E838 (5.5 x10^4 CFU/mL)	 100% (6/6) 100% (6/6)
BPP High Positive	 4 4	**100X LOD** BPP A747 (4.6 x10^5 CFU/mL) BPP E838 (5.5 x10^5 CFU/mL)	 100% (4/4) 100% (4/4)
Negative Control	6	**N/A**	0% (0/6)
BPP Positive Control	6	**N/A**	100% (6/6)

The Solana Bordetella Complete Assay demonstrated 100% percent agreement to three (3) concentrations of *Bordetella parapertussis* (BPP) (two (2) strains). This observation is based on the following findings:

- All negative samples generated negative results for BPP.
- The detection percentage of BPP Low samples is 100% (10/10).

- The detection percentage of BPP Moderate samples was 100% (6/6).
- The detection percentage of BPP High samples was 100% (4/4).
- The Positive and Negative controls performed as expected:
  - The detection percentage of BPP in the positive control was 100% (6/6).
  - The detection percentage of BP and BPP in the negative control was 0% (0/6)

ANALYTICAL PERFORMANCE

Limit of Detection

The analytical sensitivity (limit of detection or LOD) of the Solana Bordetella Complete Assay was determined using quantified (CFU/mL) cultures of two (2) BP strains (A639 and E431) and two (2) BPP strains (A747 and E838) serially diluted in a negative nasal matrix.

Target Type	Target	Validation Lot	Determined LOD	
			CFU/mL	CFU/Assay
Fresh Cells	BP Strain: A639	1	1025	1.71
		2	1025	1.71
		3	1025	1.71
	BP Strain: E431	1	863	1.44
		2	863	1.44
		3	863	1.44
	BPP Strain: A747	1	4622	7.70
		2	4622	7.70
		3	4622	7.70
	BPP Strain: E838	1	5533	9.22
		2	5533	9.22
		3	5533	9.22
Assay LOD: BP			1025	1.71
Assay LOD: BPP			5533	9.22

Analytical Reactivity (Inclusivity)

The reactivity of the Solana Bordetella Complete Assay was evaluated against an additional eight (8) *Bordetella pertussis* (BP) and eight (8) *Bordetella parapertussis* (BPP) strains that were not used for LOD determination. The testing was performed at 1x LOD (1025 CFU/mL and 5533 CFU/mL, respectively) level of the assay. All additional sixteen (16) strains were detected in the Solana Bordetella Complete Assay.

BP Strains Detected at 1X LOD (1025 CFU/mL)	BPP Strains Detected at 1X LOD (5533 CFU/mL)
GBS Strain	**Serotype**
ATCC® 9340	ZeptoMetrix C510
ATCC 9797	ZeptoMetrix E595
ATCC BAA-1335	ATCC 15311
ATCC BAA-589	ATCC 15989
ATCC 51445	ATCC 53892
ATCC 10380	ATCC 53893
ATCC 8478	ATCC BAA-587
ATCC 12743	ATCC 15237

Analytical Specificity – Microbial Interference

A study was performed to determine if eighty-three (83) microorganisms or viruses likely to be present in specimens collected to test for *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) infection interfered with the Solana Bordetella Complete Assay. One (1) BP strain (A639) and one (1) BPP strain (E838) were tested at 2x LOD (2050 CFU/mL and 11066 CFU/mL, respectively) in the Solana Bordetella Complete Assay. The microorganisms were tested above clinically relevant levels (bacteria ≥ $1x10^6$ CFU/mL, viruses the ≥ $1x10^5 TCID_{50}$/mL).

Organism – Bacteria		
Acinetobacter baumanii	*Bordetella pertussis A639*	*Legionella pneumophilia*
Arcanobacterium haemolyticum	*Bordetella petrii*	*Moraxella catarrhalis*
Bacteroides fragilis	*Bordetella trematum*	*Morganella morganii*
Bordetella avium	*Burkholderia cenocepacia*	*Mycobacterium avium*
Bordetella bronchiseptica (ATCC 780)	*Burkholderia cepacia*	*Mycobacterium tuberculosis (avirulent)*
Bordetella bronchiseptica (ZeptoMetrix 801649)	*Burkholderia multivorans*	*Mycoplasma pneumoniae*
Bordetella bronchiseptica (ATCC 4617)	*Burkholderia thailandensis*	*Neisseria gonorrhoeae*
Bordetella bronchiseptica (ATCC 10580)	*Chlamydia trachomatis*	*Neisseria meningitidis*
Bordetella bronchiseptica (ATCC BAA-588)	*Chlamydophila pneumoniae*	*Neisseria mucosa*
Bordetella bronchiseptica (ATCC 785)	*Corynebacterium diptheriae*	*Parvimonas micra*
Bordetella bronchiseptica (ATCC 786)	*Enterobacter aerogenes*	*Proteus mirabilis*
Bordetella bronchiseptica (ATCC 14064)	*Enterococcus faecalis*	*Proteus vulgaris*
Bordetella hinzii	*Escherichia coli*	*Pseudomonas aeruginosa*
Bordetella holmesii (ZeptoMetrix F061)	*Fusobacterium necrophorum*	*Staphylococcus aureus (MRSA)*
Bordetella holmesii (ATCC 51541)	*Haemophilus influenzae*	*Staphylococcus epidermidis*
Bordetella holmesii (ATCC 700053)	*Klebsiella pneumoniae*	*Stenotrophomonas maltophilia*
Bordetella holmesii (ATCC 700052)	*Lactobacillus acidophilus*	*Streptococcus pneumoniae*
Bordetella parapertussis E838	*Lactobacillus plantarum*	*Streptococcus pyogenes*
		Streptococcus salivarius

Organism – Yeast
Candida albicans

Organism – Virus	
Adenovirus 31	HSV Type 2 G strain
Coronavirus 229E	Influenza A/Mexico/4108/2009
Coronavirus NL63	Influenza B/Florida/04/2006
Coronavirus OC43	Measles virus
Coxsackievirus B4	Metapneumovirus A1
Coxsackievirus B5/10/2006	Mumps virus
Echovirus 6	Parainfluenza Type 1 (#2)
Echovirus 7	Parainfluenza Type 2 (Greer)
Echovirus 9	Parainfluenza Type 3 (C234)
Echovirus 11	Parainfluenza Type 4 (VR-1377)
Enterovirus 70	Respiratory Syncytial Virus A
Enterovirus 71	Rhinovirus 1A
Epstein-Barr Virus	Varicella Zoster Virus
HSV Type 1 Maclnytre strain	

None (0) of the organisms or viruses tested above interfered with the performance of the Solana Bordetella Complete Assay.

High levels of BP A639 did not cause interference with BPP E838 detection, and high levels of BPP E838 did not cause interference with BP A639 detection.

Analytical Specificity – Microbial Cross-reactivity

A study was performed to determine if eighty-three (83) microorganisms or viruses likely to be present in specimens collected to test for *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) infection cross-react with the Solana Bordetella Complete Assay. The microorganisms were tested above clinically relevant levels (bacteria ≥ $1x10^6$ CFU/mL, viruses the ≥ $1x10^5 TCID_{50}$/mL).

Organism – Bacteria		
Acinetobacter baumanii	*Bordetella pertussis A639*	*Legionella pneumophilia*
Arcanobacterium haemolyticum	*Bordetella petrii*	*Moraxella catarrhalis*
Bacteroides fragilis	*Bordetella trematum*	*Morganella morganii*
Bordetella avium	*Burkholderia cenocepacia*	*Mycobacterium avium*
Bordetella bronchiseptica (ATCC 780)	*Burkholderia cepacia*	*Mycobacterium tuberculosis (avirulent)*
Bordetella bronchiseptica (ZeptoMetrix 801649)	*Burkholderia multivorans*	*Mycoplasma pneumoniae*
Bordetella bronchiseptica (ATCC 4617)	*Burkholderia thailandensis*	*Neisseria gonorrhoeae*
Bordetella bronchiseptica (ATCC 10580)	*Chlamydia trachomatis*	*Neisseria meningitidis*
Bordetella bronchiseptica (ATCC BAA-588)	*Chlamydophila pneumoniae*	*Neisseria mucosa*
Bordetella bronchiseptica (ATCC 785)	*Corynebacterium diptheriae*	*Parvimonas micra*
Bordetella bronchiseptica (ATCC 786)	*Enterobacter aerogenes*	*Proteus mirabilis*
Bordetella bronchiseptica (ATCC 14064)	*Enterococcus faecalis*	*Proteus vulgaris*
Bordetella hinzii	*Escherichia coli*	*Pseudomonas aeruginosa*
Bordetella holmesii (ZeptoMetrix F061)	*Fusobacterium necrophorum*	*Staphylococcus aureus (MRSA)*
Bordetella holmesii (ATCC 51541)	*Haemophilus influenzae*	*Staphylococcus epidermidis*
Bordetella holmesii (ATCC 700053)	*Klebsiella pneumoniae*	*Stenotrophomonas maltophilia*
Bordetella holmesii (ATCC 700052)	*Lactobacillus acidophilus*	*Streptococcus pneumoniae*
Bordetella parapertussis E838	*Lactobacillus plantarum*	*Streptococcus pyogenes*
		Streptococcus salivarius

Organism – Yeast
Candida albicans

Organism – Virus	
Adenovirus 31	HSV Type 2 G strain
Coronavirus 229E	Influenza A/Mexico/4108/2009
Coronavirus NL63	Influenza B/Florida/04/2006
Coronavirus OC43	Measles virus
Coxsackievirus B4	Metapneumovirus A1
Coxsackievirus B5/10/2006	Mumps virus
Echovirus 6	Parainfluenza Type 1 (#2)
Echovirus 7	Parainfluenza Type 2 (Greer)
Echovirus 9	Parainfluenza Type 3 (C234)
Echovirus 11	Parainfluenza Type 4 (VR-1377)
Enterovirus 70	Respiratory Syncytial Virus A
Enterovirus 71	Rhinovirus 1A
Epstein-Barr Virus	Varicella Zoster Virus
HSV Type 1 Maclnytre strain	

Five (5) non-BP organisms tested positive for BP. The five (5) organisms include 4 of 4 *Bordetella holmesii* strains (ZeptoMetrix F061, ATCC 51541, ATCC 700053, and ATCC 700052) and 1 of 8 *Bordetella bronchiseptica* strains (ATCC 4617). Cross reactivity with these organisms is expected due to the presence of the BP target sequence, IS481, in the genomes of these organisms.

None (0) of the potentially cross-reactive organisms tested positive for BPP.

High levels of BP did not generate any BPP-positive results, and high levels of BPP did not generate any BP-positive results, which indicate that the Solana Bordetella Complete Assay is specific for each target.

Analytical Specificity – Interfering Substances

The performance of Solana Bordetella Complete Assay was evaluated with sixteen (16) potentially interfering substances that may be present in specimens collected to test for *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP). The substances were diluted in negative nasal matrix and tested in the absence or presence of 2x LOD BP (Strain A639 2050 CFU/mL) and 2x LOD BPP (Strain E838 11066 CFU/mL) in the Solana Bordetella Complete Assay.

Substance	Concentration Tested	Substance	Concentration Tested
Cepacol Sore Throat Lozenges	5% w/v	Neo-Synephrine	15% v/v
Halls Cherry Menthol-Lyptus Cough Drops	15% w/v	Afrin Nasal Spray Original	15% v/v
Children's Dimetapp	15% v/v	Zicam Non-Drowsy Allergy Relief Nasal Gel	5% v/v
Chloraseptic Sore Throat Lozenges	10% w/v	Rite Aid Brand Saline Nasal Spray	15% v/v
Ricola Original Swiss Sugar-Free Herb Cough Suppressant Throat Drops	15% w/v	Zanamivir (Relenza)	5 mg/mL
Sucrets Complete Lozenges - Vapor Cherry	5% w/v	Tobramycin	4 µg/mL
Mucin (Bovine Submaxillary Gland, Type I-S)	5 mg/mL	Mupirocin	10 mg/mL
Human Blood, EDTA anticoagulated	5% v/v	Oseltamivir Phosphate (Tamiflu)	10 mg/mL

Negative sample testing in the presence of each of the sixteen (16) substances produced negative results for 3 of 3 replicates. BP+BPP sample testing at 2x LOD levels in the presence of each of the 16 substances produced BP and BPP positive results for 3 of 3 replicates. Based on these results, the 16 substances tested in this study are considered to not interfere with the Solana Bordetella Complete Assay.

Fresh versus Frozen Equivalence Study

A study was performed to demonstrate equivalency between fresh and frozen specimens. Two (2) BP strains (A639 and E431) and two (2) BPP strains (A747 and E838) were serially diluted in a negative nasal matrix at varying concentrations above and below the assay LOD. The dilutions were tested fresh and then frozen at −70°C. The dilutions demonstrating at least 95% detection (≥19 of 20) were thawed and re-tested. For all 4 organisms strains tested, the fresh and frozen results matched at LOD concentrations indicating equivalence between fresh and frozen samples when tested with the Solana Bordetella Complete Assay.

Reproducibility Study

A four-sample panel consisting of three (3) levels of a combined BP and BPP (two (2) strains of each organism) contrived samples and a negative contrived sample were tested in this study. BP A639 and BPP A747 (Set 1), or BP E431 and BPP E838 (Set 2) were diluted in negative nasal matrix to 2x LOD for moderate positive, 1x LOD for low positive and diluted to concentrations below the LOD (i.e., C_{20} to C_{80}) for high negative samples. Negative nasal matrix without spiked organism was used for the negative sample. Positive and negative controls were run in triplicate along with the panels. The panels were run by two (2) operators at each testing site for five (5) non-consecutive days. The Solana Bordetella Complete Assay was used per the instructions for use.

Panels and controls were tested at each site by two (2) operators per instrument for five (5) days, each sample tested in three (3) replicates, for a total of 45 results per level for each organism strain (2 operators x 5 days x 3 sites x 3 replicates).

Reproducibility Summary									
Reproducibility Samples	SITE						Overall Percent Agreement		95% Confidence Interval
	Site #1		Site #2		Site #3				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
BP strain A639 High Negative[1]	7/15	46.6	7/15	46.6	6/15	40.0	20/45	44.4	30.9 to 58.8

Reproducibility Summary									
Reproducibility Samples	**SITE**						**Overall Percent Agreement**		**95% Confidence Interval**
	Site #1		**Site #2**		**Site #3**				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
(103 CFU/mL)									
BP strain A639 Low Positive (1025 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain A639 Moderate Positive (2050 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain E431 High Negative (86 CFU/mL)	4/15	26.7	10/15	66.7	7/15	46.6	21/45	46.7	32.9 to 60.9
BP strain E431 Low Positive (862 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain E431 Moderate Positive (1724 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain A747 High Negative[1] (462 CFU/mL)	6/15	40.0	7/15	46.6	1/15	6.7	14/45	31.1	19.5 to 45.7
BPP strain A747 Low Positive (4622 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain A747 Moderate Positive (9244 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain E838 High Negative (553CFU/mL)	6/15	40.0	8/15	53.3	3/15	20.0	17/45	37.8	25.1 to 52.4
BPP strain E838 Low Positive (5533 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain E838 Moderate Positive (11,066 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
Negative Sample	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100
BP Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
BPP Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100

[1] An expected result for the high negative sample is percent positivity between 20 and 80%.

Carryover – Cross Contamination

A study was conducted to demonstrate that carry-over and cross contamination does not occur when the intended users perform the Solana Bordetella Complete Assay following PI instructions.

Two (2) samples were prepared: BP positive sample and BP negative sample. The positive sample was prepared by adding cells of one (1) BP strain with a known titer to negative nasal matrix at the concentration of $1x10^6$ CFU/mL.

The negative nasal matrix served as the BP negative sample. In each experiment, the positive samples were alternated with the negative samples and tested using Solana Bordetella Complete Assay to assess the risk of cross contamination. In total, two (2) operators tested a total of 30 positive and 30 negative samples over a total of five (5) runs.

All positive BP samples were positive and all negative samples were negative. No evidence of carry-over/cross contamination was observed with the Solana Bordetella Complete Assay when performed in accordance with the package insert.

CUSTOMER AND TECHNICAL ASSISTANCE

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

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GLOSSARY

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult e-labeling instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 48 determinations
CONT Contents/Contains	