

# Comparison of a novel PCR assay for *Bordetella pertussis* detection with a Helicase Based Assay

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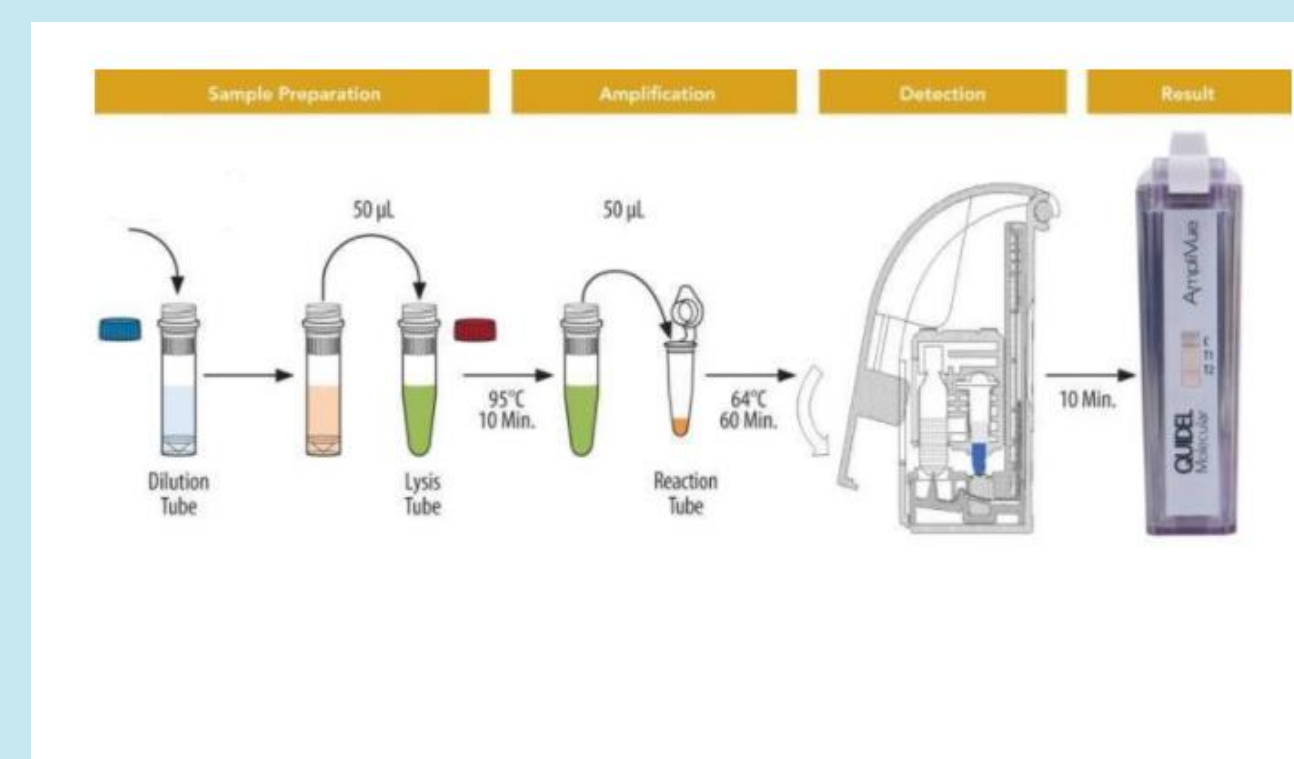
## Introduction

*Bordetella pertussis* and *Bordetella parapertussis* are gram negative coccobacilli that are responsible for pertussis or whooping cough. Early detection of *B. pertussis* is vital for proper treatment. Culture is the gold standard, but can take 5-7 days for a result. Therefore molecular methods are the preferred modality for detecting these bacterium.

## Methods

- 148 frozen specimens that were previously run on the Quidel AmpliVue® *Bordetella* Helicase assay were run on the DiaSorin Simplexa™ *Bordetella* Direct PCR Assay.
- Specimens were all originally collected in universal transport media.
- Positive and Negative results were compared from each assay.

### AmpliVue® *Bordetella* Helicase



### Simplexa™ *Bordetella* Direct PCR Assay



## Acknowledgments

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- Hershey Medical Center Virology Technologists
- DiaSorin Molecular, LLC

## Results

### Simplexa™ PCR Assay vs. AmpliVue® Helicase Assay

	Simplexa™ Positive	Simplexa™ Negative
AmpliVue® Positive	10	0
AmpliVue® Negative	4 <sup>a</sup>	133 <sup>b</sup>

a. 3 samples were positive for *B. pertussis* and 1 was positive for *B. parapertussis*

b. 1 sample had repeat errors on the Simplexa™ platform and was not included in statistical analysis

### Cycle Threshold Values

Sample #	Originally Positive	Simplexa Ct	Repeat Ct
001	Yes	27.4	-
007	Yes	29.6	-
031	Yes	30.8	-
037	Yes	19.4	-
045	Yes	15.1	-
106	Yes	30.0	-
126	Yes	28.0	-
136	Yes	28.0	-
008	No	38.2	Negative
013	No	33.1	34.5
057	No	29.6	29.2

## Conclusions

- Simplexa™ *Bordetella* Assay has a single step hands-on time of 10 minutes for 8 samples and total run time ~70 minutes.
- Quidel AmpliVue® has multiple hands-on steps with a >90 minute turn around time.
- Simplexa™ requires a LIAISON® MDX cyclor. Quidel AmpliVue® requires two heat blocks.
- PCR assay detected 3 positive *B. pertussis* results that the helicase assay called negative and 1 positive *B. parapertussis* that could not be identified on the helicase assay.
- 1 of those *B. pertussis* results was negative on repeat PCR testing.
- Simplexa™ is able to detect *B. pertussis* and *B. parapertussis*.
- AmpliVue® is able to detect *B. pertussis* only.
- Samples that are positive with a high Ct on PCR may be missed by helicase assay.
- Simplexa™ PCR Assay demonstrated equal or greater sensitivity compared to AmpliVue® Helicase assay.