

Summary of 2019 Annual Flu Strain Reactivity testing

Catalog 256045: BD Veritor™ System for Rapid Detection of Flu A + B, CLIA-Waived kit

A panel of eight human influenza viral strains was provided by the Centers for Disease Control for evaluating the reactivity of the BD Veritor™ System Flu A+B CLIA-waived test, as required by CFR 866.3328. The viral isolates included four Influenza A and four Influenza B strains. Each sample was serially diluted in five-fold dilutions from the stock provided and each dilution was assayed in replicates of five. To create samples for testing, mock patient samples were prepared by pipetting 50 µL of each diluted sample onto a swab. Each swab was tested following the procedure included in the BD product package insert.

All strains were successfully detected. The concentrations highlighted below identify the lowest dilution at which any of the five replicates gave a positive reading.

Results²:

| Influenza Virus Type/(Subtype) | Virus Strain Name | Stock EID ₅₀ /mL | Virus Serial Dilution Concentration (EID ₅₀ /mL) and Number of Positive Results at Each Dilution | | | | | | | |
|--------------------------------|-------------------------|-----------------------------|---|---------------------|---------------------|-----------------------------|-----------------------------|-----------------------------|------------------------|------------------------|
| | | | 2×10 ^{7.3} | 4×10 ^{6.3} | 8×10 ^{5.3} | 1.6×10 ^{5.3} | 3.2×10 ^{4.3} | 6.4×10 ^{3.3} | 1.28×10 ^{3.3} | |
| A (H3N2) | A/Perth/16/2009 | 10 ^{8.3} | 2×10 ^{7.3} | 4×10 ^{6.3} | 8×10 ^{5.3} | 1.6×10 ^{5.3} | 3.2×10^{4.3} | 6.4×10 ^{3.3} | 1.28×10 ^{3.3} | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | |
| | A/Kansas/14/2017 * | 10 ^{8.9} | 2×10 ^{7.9} | 4×10 ^{6.9} | 8×10 ^{5.9} | 1.6×10 ^{5.9} | 3.2×10^{4.9} | 6.4×10 ^{3.9} | 1.28×10 ^{3.9} | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | |
| A (H1N1)pdm09 | A/Christ Church/16/201 | 10 ^{9.9} | 2×10 ^{8.9} | 4×10 ^{7.9} | 8×10 ^{6.9} | 1.6×10 ^{6.9} | 3.2×10^{5.9} | 6.4×10 ^{4.9} | 1.28×10 ^{4.9} | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | |
| | A/Brisbane/02/2018 * | 10 ^{7.9} | 2×10 ^{6.9} | 4×10 ^{5.9} | 8×10 ^{4.9} | 1.6×10 ^{4.9} | 3.2×10 ^{3.9} | 6.4×10^{2.9} | 1.28×10 ^{2.9} | 2.56×10 ^{1.9} |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 5/5 | 1/5 | 0/5 | 0/5 |
| B (Victoria lineage) | B/Michigan/09/2011 | 10 ^{8.5} | 2×10 ^{7.5} | 4×10 ^{6.5} | 8×10 ^{5.5} | 1.6×10^{5.5} | 3.2×10 ^{4.5} | 6.4×10 ^{3.5} | | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | | |
| | B/Colorado/06/2017 * | 10 ^{8.3} | 2×10 ^{7.3} | 4×10 ^{6.3} | 8×10 ^{5.3} | 1.6×10^{5.3} | 3.2×10 ^{4.3} | 6.4×10 ^{3.3} | | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | | |
| B (Yamagata lineage) | B/New Hampshire/01/2016 | 10 ^{8.9} | 2×10 ^{7.9} | 4×10 ^{6.9} | 8×10 ^{5.9} | 1.6×10^{5.9} | 3.2×10 ^{4.9} | 6.4×10 ^{3.9} | | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | | |
| | B/Phuket/3073/2013 * | 10 ^{8.9} | 2×10 ^{7.9} | 4×10 ^{6.9} | 8×10 ^{5.9} | 1.6×10^{5.9} | 3.2×10 ^{4.9} | 6.4×10 ^{3.9} | | |
| | | | 5/5 | 5/5 | 5/5 | 5/5 | 0/5 | 0/5 | | |

*Strains recommended by CDC for inclusion in Northern Hemisphere vaccine for 2019-2020

²all samples consisted of 50 µL of diluted viral sample on a swab identical to those contained in the BD Veritor™ CLIA Waived Flu kit. Results with actual patient samples may vary.