

Rapid Diagnostics Reliable Protection



VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay Performance

The VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay consistently demonstrates high clinical performance, accuracy, and sensitivity across multiple studies. Comparative analyses against established assays like Cepheid Xpert® CoV-2/Flu/RSV Plus Assay and Seegene Allplex™ SARS-CoV-2 Assay confirm its strong agreement for SARS-CoV-2, Flu A, Flu B, and RSV, notably achieving 100% agreement with Seegene Allplex™ SARS-CoV-2 Assay for SARS-CoV-2 detection, eliminating false positives or negatives. Its analytical sensitivity, as evidenced by its Limit of Detection (LoD) across various viral strains, allows for consistent detection even at low viral concentrations, supporting early diagnosis and detection in low viral load scenarios. Furthermore, the assay's ability to consistently detect SARS-CoV-2 across all viral load ranges (100% positive rate) ensures reliable diagnosis at any stage of infection. Collectively, these studies highlight the VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay as a highly reliable, accurate, and sensitive multiplex diagnostic tool, providing clinicians with robust confidence for precise patient management, effective infection control, and streamlined workflows in diagnosing common respiratory viral infections.

VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay Performance Summary in Clinical Nasal Samples Comparing to Cepheid Xpert® CoV-2/Flu/RSV Plus Assay

| | | Cepheid Xpert® CoV-2/Flu/RSV Plus Assay | | | | |
|---|----------|---|----------------|----------------|--------------|----------|
| | | SARS-CoV-2 Positive | Flu A Positive | Flu B Positive | RSV Positive | Negative |
| VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay | Positive | 171 | 122 | 45 | 3 | 0 |
| | Negative | 3 | 6 | 1 | 0 | 102 |
| | Total | 174 | 128 | 46 | 3 | 102 |
| Positive Percentage Agreement (PPA) | | 98.3% | 95.3% | 97.8% | 100% | |
| Negative Percentage Agreement (NPA) | | 100% | 100% | 100% | 100% | |
| Overall Percentage Agreement (OPA) | | 98.9% | 97.4% | 100% | 100% | |

This table presents the clinical performance of the VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay in comparison to the Cepheid Xpert® CoV-2/Flu/RSV Plus Assay. A comprehensive clinical study was conducted using 453 nasal samples, including 174 SARS-CoV-2 positive, 122 Flu A positive, 45 Flu B positive, 3 RSV positive, and 102 negative samples. The results demonstrate the VitaSIRO solo™ Assay's strong agreement and high accuracy across all tested viral targets.

VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay Performance Summary in Clinical Nasal Samples Comparing to Seegene Allplex™ SARS-CoV-2 Assay

| | | Seegene Allplex™ SARS-CoV-2 Assay | |
|---|----------|-----------------------------------|----------|
| | | SARS-CoV-2 Positive | Negative |
| VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay | Positive | 107 | 0 |
| | Negative | 0 | 152 |
| | Total | 107 | 152 |
| Positive Percentage Agreement (PPA) | | 100% | 0% |
| Negative Percentage Agreement (NPA) | | 0% | 100% |
| Overall Percentage Agreement (OPA) | | 100% | |

This table showcases the exceptional performance of the VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay when compared against the Seegene Allplex™ SARS-CoV-2 Assay, a primary comparator method. In a comprehensive clinical study involving 259 nasal samples (107 positive and 152 negative for SARS-CoV-2), the VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay demonstrated a 100.00% Positive Percentage Agreement (PPA), a 100.00% Negative Percentage Agreement (NPA), and a 100% Overall Percentage Agreement (OPA).



Limit of Detection of VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay

| VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay | | | | | | |
|---|--|---|---|---|---|---|
| SARS-CoV-2 | Flu A | | Flu B | | RSV A | RSV B |
| | H1N1pdm09 (California/07/09) | H3N2 (Victoria/361/11) | Victoria Lineage (Texas/2/13) | Yamagata Lineage (Panama/45/90) | 3/2015 Isolate #3 | 3/2015 Isolate #1 |
| 5.75×10^{-1} TCID ₅₀ /mL | 7.1×10^{-1} TCID ₅₀ /mL | 1.04×10^{-2} TCID ₅₀ /mL | 7.05×10^{-3} TCID ₅₀ /mL | 1.41×10^{-2} TCID ₅₀ /mL | 1.25×10^{-1} TCID ₅₀ /mL | 3.89×10^{-3} TCID ₅₀ /mL |

| Cepheid Xpert® CoV-2/Flu/RSV Plus Assay | | | | | | |
|---|--|---------------------------|----------------------------------|------------------------------------|--|--|
| SARS-CoV-2 | Flu A | | Flu B | | RSV A | RSV B |
| | H1N1pdm09 (California/07/09) | H3N2 (Victoria/361/11) | Victoria Lineage (Texas/2/13) | Yamagata Lineage (Panama/45/90) | 3/2015 Isolate #3 | 3/2015 Isolate #1 |
| 138 copies/mL | 7.1×10^{-3} TCID ₅₀ /mL | - | 2.4 TCID ₅₀ /mL | - | 3.3×10^{-1} TCID ₅₀ /mL | 3.7×10^{-1} TCID ₅₀ /mL |

This table above demonstrates the study which were conducted to evaluate the limit of detection (LoD) that analytes can be consistently detected at the lowest concentration by VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay.

Diagnosis of Different Viral Loads

| Ct Range | Positive Rate | Ct Value Distribution |
|----------|---------------|-----------------------|
| >35 | 11/11 | 10.7% |
| >30~35 | 12/12 | 11.7% |
| 25~30 | 39/39 | 37.9% |
| <25 | 41/41 | 39.8% |
| Total | 103/103 | 100% |

This table demonstrates the performance of two diagnostic assays—the VitaSIRO solo™ SARS-CoV-2/Flu/RSV Assay and the Seegene Allplex™ SARS-CoV-2 Assay—across different ranges of SARS-CoV-2 viral loads. The Ct values are categorized into four distinct groups based on established guidelines: high viral load (Ct < 25), high-medium (Ct 25–30), low-medium (Ct > 30–35), and low viral load (Ct > 35). The table provides a snapshot of the viral load distribution among the detected cases.

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Version 1.0: June 2025

