

**Transforming healthcare** at the point of need





#### HbA1c

Lab-comparable results in less than 7 minutes at the point of care

Monitor known diabetic patients' HbA1c levels at the point of need - improved efficiencies and convenience with on-the-spot diabetes screening at the patient's side.

Actionable, lab-comparable results from a single fingerstick sample.



- Sample types: fingerstick or venous whole blood (EDTA), via lysis device
- Sample size: 15 µL
- Measuring range: 20 130 mmol/mol (4.0 -14.0%)
- Time to result: <7 minutes
- Storage at room temperature (2°C to 30°C)



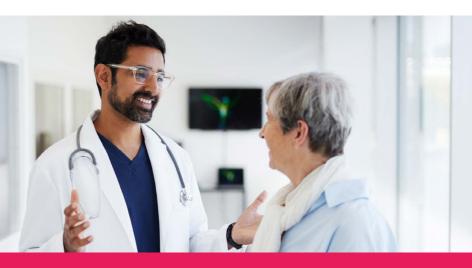
CRP Rapidly identify CRP levels in just 4 minutes

A quantitative, direct fingerstick, determination of C-Reactive Protein. Help identify infection, tissue injury, inflammation disorders.

- Sample types: direct fingerstick (or via lithium heparin transfer tube), venous (lithium heparin), or plasma (lithium heparin)
- Sample size: 20 μL
- Hematocrit determination for whole blood sample to ensure 15 - 55% range
- Reportable range 5 250 mg/L
- Time to result: 4 minutes
- Storage at room temperature (2°C to 30°C)

patients.





#### **D-Dimer**

**Exclude VTE with confidence** in only 6 minutes

Rapidly quantify D-Dimer levels in human whole blood and plasma. The only\* quantitative, direct fingerstick test that can be used to rule out potential VTE alongside pre-test probability scores in symptomatic



- Improve efficiencies by rapidly excluding deep vein thrombosis (DVT) and pulmonary embolism (PE)
- Clinical Cut-off: 500 µg/L FEU, 0.500 mg/L FEU
- · Sample types: direct fingerstick (or via lithium heparin transfer tube), venous (sodium citrate) or plasma (sodium citrate)
- Sample size: 15 µL
- Hematocrit determination for whole blood sample to ensure 20 - 55% range
- Reportable range 190 4000 µg/L (FEU) or 0.190 - 4.000 mg/L (FEU)
- Time to result: 6 minutes
- Storage at room temperature (2°C to 30°C)

**NT-proBNP** 

The only<sup>\*</sup> direct fingerstick NT-proBNP test available at the point of care

Rapidly quantify NT-proBNP levels in only 12 minutes without needing a phlebotomist. Used to aid in the diagnosis of congestive heart failure wherever symptomatic patients present.



- Sample types: direct fingerstick (or via lithium heparin transfer tube), venous (lithium heparin), or plasma (lithium heparin)
- Sample size: 20 µL
- Hematocrit determination for whole blood sample to ensure 15 - 55% range
- Reportable range 50 9,000 pg/mL (ng/L)
- Time to result: 12 minutes
- Storage at room temperature (2°C to 30°C)

\* As of 24 May 2022



### INR

#### Rapid, reliable, lab-comparable INR results - at the patient's side

Monitor your patient's vitamin-K antagonist (VKA) therapy with lab comparable results and direct fingerstick sampling at the point of care.

- Sample type: direct fingerstick (or non-anticoagulated transfer tube)
- Sample size: 8 µL
- · Hematocrit determination for whole blood sample to ensure 25 - 55% range
- Reportable range 0.8 7.5 INR
- Time to result: 60 90 secs\*
- Storage at room temperature (5°C to 32 °C)



## SARS-CoV-2 Ag Ultra

Rapidly identify COVID-19 in just 5 minutes

Optimize your clinical workflow, verify potential infection quickly and help triage patients without delay. Actionable lab-comparable results for patients suspected of COVID-19.



 Optimize clinical workflows - accurately and confidently test more patients

- Sample type: nasal swab • High sensitivity to Ct <34 within 12 days of the onset of symptoms
- Nasal swabs:
- 97.4%\* PPA versus RT-PCR with symptoms
- 95.7% PPA versus RT-PCR without symptoms
- 100% NPA
- Time to result: 5 minutes
- Storage at room temperature (2°C to 30°C)

\* Ct <34 Refer to SARS-CoV-2 Ag Ultra Product Insert for full clinical data



\* Supratherapeutic INR >4.0 test result could take 90 - 180 secs



#### SARS-CoV-2 Ag Ultra Pool

Rapidly identify COVID-19, test 5 samples in just 5 minutes

Verify that COVID-19 isn't spreading in your population. Quickly and easily scale up your testing with actionable lab-comparable and cost-efficient results for pooled patient samples.

- Save time: pooled testing can result in a 40 - 60% reduction in testing time and resources
- Sample type: nasal swab
- 93.1%\* PPA versus RT-PCR
- Time to result: 5 minutes for up to 5 pooled samples
- Storage at room temperature (2°C to 30°C)



#### SARS-CoV-2 & Flu A/B

Is it Flu? Is it COVID-19? Actionable results in 12 minutes

Verify potential infection quickly, 1 sample - 3 actionable and lab-comparable results for patients suspected of Flu and/or COVID-19. Help decision making and guide treatment.



- · Optimize patient and clinical flow -1 sample, 3 results, 12 minutes
- Test: Flu A, Flu B and COVID-19
- Sample types: nasal swab
- SARS-CoV-2 Ag:
  - PPA\* up to 95.5% NPA\* up to 99.0%
- Flu A: PPA 83.3% NPA 97.6%
- Flu B: PPA 80% NPA 94.9%
- Time to result: 12 minutes
- Storage at room temperature (2°C to 30°C)

\*Based on 0-12 days since symptom onset data. Refer to SARS-CoV-2 & Flu A/B Product Insert for full clinical data

\* Ct <34 Refer to SARS-CoV-2 Ag Ultra Pool Product Insert for full clinical data



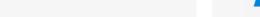
#### SARS-CoV-2 & RSV

Identify RSV and COVID-19, 1 sample, 2 results, 12 minutes

Verify potential infection and help guide infection control measures quickly. Actionable results, for patients suspected of RSV and/or COVID-19.



- Optimize patient and clinical flow
- 1 sample, 2 results, 12 minutes
- Test: RSV and COVID-19
- Sample type: nasal swab
- SARS-CoV-2
- PPA \* 97.4%
- RSV
- PPA\*\* 80%
- Time to result: 12 minutes
- Storage at room temperature (2°C to 30°C)



\*Ct <33 \*\* Ct <30 Refer to SARS-CoV-2 & RSV Product Insert for full clinical data



#### SARS-CoV-2 Ag

Verify COVID-19 quickly, lab-comparable results in 12 minutes

Identify potentially infected and contagious spreaders quickly. Actionable and lab-comparable results for patients suspected of COVID-19.



Sample types: nasal and nasopharyngeal swab

- Nasal swabs (symptomatic) - 97.6%\* PPA versus RT-PCR
- 96.6% NPA versus RT-PCR
- Nasal swabs (asymptomatic)
- 82.4% PPA versus RT-PCR
- 99.3% NPA versus RT-PCR
- Time to result: 12 minutes
- Storage at room temperature (2°C to 30°C)



\* Ct <33 Refer to SARS-CoV-2 Ag Product Insert for full clinical data



#### **SARS-CoV-2 Ag Pool**

Verify COVID-19 quickly, test 5 samples in 12 minutes

Identify potentially contagious spreaders and verify that COVID-19 isn't spreading in your population. Scale up your testing with actionable, lab-comparable and cost-efficient results for pooled patient samples.

- Save time: pooled testing can result in a 40 60% reduction in testing time and resources
- Sample type: nasal swab
- 100% PPA and 96.6% NPA when compared to LumiraDx SARS-CoV-2 Ag test
- Time to result: 12 minutes for up to 5 pooled samples
- Storage at room temperature (2°C to 30°C)



#### SARS-CoV-2 Ab

Quickly identify a recent COVID-19 infection in just 11 minutes

Identify individuals with an adaptive immune response to COVID-19, therefore indicating recent or prior infection. Actionable and lab-comparable results.



- Qualitative detection of total antibodies
- Sample types: direct fingerstick (or via non-anticoagulated transfer tube), venous whole blood (EDTA), plasma (EDTA) or serum
- Sample size: 20 µL
- Hematocrit determination for whole blood sample to ensure 25 - 55% range
- Time to result: 11 minutes
- Storage at room temperature (2°C to 30°C)

# Vorking to ensure the future of diagnostics should be one that benefits everyone, everywhere.

Contact Us. We are looking forward to your call!

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