



Celltrion DiaTrust COVID-19 Ag Rapid Test and Home Test Kits Procurement Guide

Version 1

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Submitted to Customer:

**Applya
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Greenville, SC 29601
(833)425-2055**

Submitted by:

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I. Introduction

Soaring Eagle Pharmaceuticals, LLC, (DUNS: 081258265) a Self-Certified Service-Disabled Veteran Owned Business (CAGE:84T19) understands the important role that Applya plays in the support of the Coronavirus COVID-19 pandemic. Applya is doing their part with a critical mission in support of the domestic and international response to COVID-19 efforts.

We believe that Soaring Eagle Pharmaceuticals can be a force multiplier who can expeditiously provide Coronavirus COVID 19 Rapid Test Kits to support Applya's mission. To support public health & safety, Soaring Eagle Pharmaceuticals represents the Celltrion DiaTrust Coronavirus COVID-19 Ag Rapid Tests (POC and OTC), Novel Coronavirus (2019 SARS-CoV- SARS-CoV2) Detection Kits (Nasopharyngeal Swab)(NAICS: 325413, 339113, 423450)

II. Celltrion- DiaTrust COVID-19 Ag Home Test

Celltrion DiaTrust™ COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) of the SARS-CoV-2 spike proteins in mid-turbinate swabs from the SARS-CoV-2 virus. This test is authorized for non-prescription home use with self-collected and adult-collected direct mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset. This test is also authorized for non-prescription home use with self-collected and adult-collected mid-turbinate swab samples from individual 14 years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours (and no more than 48 hours) between tests.

Q1. Are you a manufacturer/representative for the manufacturer(s)?

A1. Soaring Eagle Pharmaceuticals is a manufacturer representative for Celltrion USA
Manufacturer Name: Celltrion

Q2. What are the unit price(s) for the product(s) presented?

A2. The per unit price for the COVID-19 Ag Home Test is \$14.50 USD based per unit kit of 2 tests per kit. 2 units per box, 120 boxes per carton and a total of 2,880 kits per pallet equal to 5,760 tests. Ground and or Air shipment not included.

Note: Pricing is subject to change at the manufacturer's discretion.

Q3. Are the products detailed in your pricing sheet subject to FDA EUA approval and oversight?

A3. The Celltrion DiaTrust COVID-19 Ag Home Test has the FDA/EUA approval effective October, 21st 2021. EUA/FDA certificate, technical specification sheet and clinical test evaluations are available upon request.

Q4. Is your organization willing to submit samples for product evaluation and testing? Be advised that sample submissions are not available at this time. However, sample submission will be coordinated at a later date.

A4. Samples of the Celltrion DiaTrust COVID-19 Ag Rapid Test may be made available upon request for independent laboratory evaluation to foreign governments, Food and Drug regulatory agencies.

III. Celltrion DiaTrust COVID-19 Ag Rapid Test (POC)

Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a rapid test based on lateral flow immunoassay intended for the qualitative detection of nucleocapsid and receptor binding domains (RBDs) from the SARS-CoV-2 in human nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity, moderate complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation

Q1. Are you a manufacturer/representative for the manufacturer(s)?

A1. Soaring Eagle Pharmaceuticals is a manufacturer representative for Celltrion USA
Manufacturer Name: Celltrion

Q2. What are the unit price(s) for the product(s) presented?

A2. The per unit price for the Celltrion DiaTrust COVID-19 Ag Rapid Test is \$5.25 USD per unit test. 25 unit tests per kit box, 24 kit boxes per carton (600 tests), 12 cartons per pallet, 7,200 tests total per pallet
Ground and or Air shipment not included.

Note: Pricing is subject to change at the manufacturer's discretion.

Q3. Are the products detailed in your pricing sheet subject to FDA EUA approval and oversight?

A3. The Celltrion DiaTrust COVID-19 Ag Rapid Test most recent revision to the FDA/EUA approval effective September, 1st 2021. EUA/FDA certificate, technical specification sheet and clinical test evaluations are available upon request.

Q4. Is your organization willing to submit samples for product evaluation and testing? Be advised that sample submissions are not available at this time. However, sample submission will be coordinated at a later date.

A4. Samples of the Celltrion DiaTrust COVID-19 Ag Rapid Test may be made available upon request for independent laboratory evaluation to foreign governments, Food and Drug regulatory agencies.

IV. STANDARD OPERATING PROCEDURES:

- 1. Customer Issues Purchase Order on their Stationary (Not to be issued via a 3rd party or Attorney/Representative) addressed to:
Soaring Eagle Pharmaceuticals, LLC. 4023 Kennett Pike Ste 448 Wilmington, DE 19807**
- 2. Customer provides Proof of Funds if not Government or U.S. Public Co.**
- 3. Celltrion USA issues invoice with shipment date (Delivery schedule)**
- 4. Wire transfer and forwarded to Celltrion as beneficiary and shipment is delivered from U.S. warehouse facility to customer provided (Name, Warehouse Address, Phones, Emails, Point of Contact)**

In closing, Soaring Eagle Pharmaceuticals is prepared and proud to support COVID-19 First Responders, Healthcare Workers and the public at large with vital COVID-19 Ag Tests that are in short supply. The outbreak of Coronavirus (COVID-19) around the world has affected every government, organization, company and individual in most parts of the world. As the situation continues to develop, we are deeply concerned about the health and safety of the global community. In-order to support the fight against the pandemic, Soaring Eagle Pharmaceuticals has changed its priorities and is stepping up its supply chain activities to align with your mission and efforts as well.

Soaring Eagle Pharmaceuticals remains committed to helping the population stay up and running during the coronavirus pandemic. We have developed new supply plans and are expanding and leveraging our capable supplier network to provide and expedite the delivery of these special items that you may need during this pandemic.