



**Notification Regarding Specimen Type Change and
Shelf-Life Extension for Celltrion DiaTrust™ COVID-19 Ag Rapid Test**

June 9, 2022

Dear Customer and Healthcare Provider,

Celltrion USA, Inc. (“Celltrion”) is committed to notifying its customers and Healthcare Providers of product updates to ensure the continuity of patient care.

The intent of this letter is to inform you that (1) the indication for use has been revised to include only the mid-turbinate nasal swab specimen type, and (2) the FDA has authorized a shelf-life extension for the Celltrion DiaTrust COVID-19 Ag Rapid Test (EUA210190).

On May 16, 2022, the specimen type for the intended use was changed to mid-turbinate nasal swabs only. The intended use excludes the claim for nasopharyngeal swabs to reduce the associated risks if the prescription use Celltrion DiaTrust COVID-19 Ag Rapid Test were distributed to patients, as they are an invasive specimen type and not suitable for patient use. An excerpt of the intended use can be found in *Appendix 1 – Table 1. Intended Use Excerpt from the Instructions for Use.*

FDA also granted Celltrion a shelf-life extension from 12 months to 18 months for the Celltrion DiaTrust™ COVID-19 Ag Rapid Tests when unopened and stored accordingly to labeled packaging and handling instructions. The affected lot numbers can be found in *Appendix 1 – Table 2. Shelf-Life Extended Lot Numbers.*

For more information, please visit our website at <https://www.celltrion.com/en-us/kit/DiaTrustAg>.

For additional questions, please contact Celltrion at 1-201-320-2023 or at celltrionusa.CS@celltrion.com.

Sincerely,

BonJoong Kim
CEO
Celltrion USA

Appendix I.

Table 1. Intended Use Excerpt from the Instructions for Use

Previous Intended Use	Updated Intended Use
<p>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-CoV2 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.</p>	<p>Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid and receptor binding domain (RBD) antigens in direct mid-turbinate nasal swab specimens from individuals who are suspected of COVID- 19 by their healthcare provider within the first 7 days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours, and no more than 48 hours, between tests.</p>

Table 2. Shelf-Life Extended Lot Numbers

Lot numbers	Printed Expiration Date (Shelf Life: 12 Months)	Extended Expiration Date (Shelf Life: 18 Months)
COVGCCF1001	2022-09-23	2023-03-23
COVGCCF1002	2022-09-27	2023-03-27
COVGCCF1003	2022-10-04	2023-04-04
COVGCCF1004	2022-10-04	2023-04-04
COVGCCF1005	2022-10-06	2023-04-06
COVGCCF1006	2022-10-10	2023-04-10
COVGCCF1007	2022-10-12	2023-04-12
COVGCCF1008	2022-10-15	2023-04-15
COVGCCF1009	2022-10-18	2023-04-18
COVGCCF1010	2022-10-20	2023-04-20
COVGCCF1009A	2022-10-18	2023-04-18
COVGCCF1011	2022-10-22	2023-04-22
COVGCCF1012	2022-10-26	2023-04-26
COVGCA1001	2022-10-20	2023-04-20
COVGCB1001	2022-10-21	2023-04-21
COVGCA1002	2022-10-24	2023-04-24
COVGCB1002	2022-10-26	2023-04-26
COVGCCF1013	2022-11-04	2023-05-04
COVGCA1003	2022-10-27	2023-04-27
COVGCB1003	2022-11-04	2023-05-04
COVGCCF1014	2022-11-05	2023-05-05
COVGCCF1015	2022-11-07	2023-05-07
COVGCA1004	2022-10-31	2023-05-01
COVGCB1004	2022-11-07	2023-05-07
COVGCCF1016	2022-11-08	2023-05-08
COVGCCF1017	2022-11-09	2023-05-09
COVGCCF1018	2022-11-10	2023-05-10
COVGCCF1019	2022-11-11	2023-05-11
COVGCA1005	2022-11-02	2023-05-02
COVGCB1005	2022-11-11	2023-05-11
COVGCCF1020	2022-11-12	2023-05-12
COVGCB1006	2022-11-14	2023-05-14
COVGCCF1021	2022-11-14	2023-05-14
COVGCA1006	2022-11-04	2023-05-04
COVGCA1007	2022-11-08	2023-05-08
COVGCCF1022	2022-11-15	2023-05-15
COVGCA1008	2022-11-10	2023-05-10
COVGCB1007	2022-11-16	2023-05-16
COVGCA1009	2022-11-12	2023-05-12
COVGCB1008	2022-11-19	2023-05-19
COVGCB1009	2022-11-23	2023-05-23
COVGCA1010	2022-11-15	2023-05-15
COVGCA1011	2022-11-16	2023-05-16
COVGCB1010	2022-11-24	2023-05-24
COVGCA1012	2022-11-18	2023-05-18

Lot numbers	Printed Expiration Date (Shelf Life: 12 Months)	Extended Expiration Date (Shelf Life: 18 Months)
COVGCA1013	2022-11-23	2023-05-23
COVGCB1011	2022-11-28	2023-05-28
COVGCB1012	2022-11-30	2023-05-30
COVGCA1017	2022-12-03	2023-06-03
COVGCA1014	2022-11-24	2023-05-24
COVGCA1015	2022-11-29	2023-05-29
COVGCA1016	2022-12-02	2023-06-02
COVGCA1018	2022-12-05	2023-06-05
COVGCB1013	2022-12-02	2023-06-02
COVGCB1014	2022-12-05	2023-06-05
COVGCB1015	2022-12-07	2023-06-07
COVGCB1016	2022-12-09	2023-06-09
COVGCB1017	2022-12-12	2023-06-12
COVGCJ2001	2023-01-18	2023-07-18
COVGCJ2002	2023-01-20	2023-07-20
COVGCJ2003	2023-01-25	2023-07-25
COVCJ2004	2023-01-26	2023-07-26
COVGCJ2005	2023-01-27	2023-07-27
COVGCJ2006	2023-01-28	2023-07-28
COVGCJ2007	2023-01-29	2023-07-29
COVGCJ2008	2023-01-30	2023-07-30
COVGCJ2009	2023-01-31	2023-07-31
COVGCJ2010	2023-02-10	2023-08-10
COVGCB2001	2023-02-10	2023-08-10
COVGCB2002	2023-02-11	2023-08-11
COVGCB2003	2023-02-12	2023-08-12
COVGCE2002	2023-01-27	2023-07-27
COVGCJ2011	2023-02-11	2023-08-11
COVGCB2005	2023-02-22	2023-08-22
COVGCE2003	2023-01-28	2023-07-28
COVGCJ2013	2023-02-13	2023-08-13
COVGCJ2014	2023-02-16	2023-08-16
COVGCJ2016	2023-02-18	2023-08-18
COVGCJ2017	2023-02-27	2023-08-27
COVGCJ2018	2023-02-28	2023-08-28
COVGCJ2019	2023-03-01	2023-09-01
COVGCB2006	2023-03-02	2023-09-02
COVGCE2004	2023-01-29	2023-07-29
COVGCCF2001	2023-02-25	2023-08-25
COVGCCF2002	2023-02-28	2023-08-28
COVGCCF2003	2022-02-27	2022-08-27
COVGCJ2015	2023-02-17	2023-08-17
COVGCJ2020	2023-03-02	2023-09-02
COVGCJ2021	2023-03-06	2023-09-06
COVGCL2001	2023-02-28	2023-08-28
COVGCJ2022	2023-03-07	2023-09-07
COVBCL2002	2023-03-01	2023-09-01

Lot numbers	Printed Expiration Date (Shelf Life: 12 Months)	Extended Expiration Date (Shelf Life: 18 Months)
COVGCB2007	2023-03-03	2023-09-03
COVBCB2008	2023-03-04	2023-09-04
COVGCCF2004	2023-03-01	2023-09-01
COVGCJ2023	2023-03-08	2023-09-08
COVGCB2009	2023-03-15	2023-09-15
COVGCJ2024	2023-03-09	2023-09-09
COVGCCF2005	2023-03-02	2023-09-02
COVGCJ2025	2023-03-10	2023-09-10
COVGCB2010	2023-03-16	2023-09-16
COVGCCF2006	2023-03-06	2023-09-06
COVGCJ2026	2023-03-11	2023-09-11
COVGCE2005	2023-02-28	2023-08-28
COVGCCF2009	2023-03-17	2023-09-17
COVGCB2014	2023-03-20	2023-09-20
COVGCB2015	2023-03-21	2023-09-21
COVGCB2016	2023-03-22	2023-09-22
COVGCJ2029	2023-03-17	2023-09-17
COVGCJ2030	2023-03-18	2023-09-18
COVGCJ2031	2023-03-19	2023-09-19
COVGCCF2010	2023-03-18	2023-09-18
COVGCB2018	2023-03-24	2023-09-24
COVGCCF2011	2023-03-21	2023-09-21
COVGCJ2032	2023-03-20	2023-09-20
COVGCJ2033	2023-03-21	2023-09-21
COVGCB2017	2023-03-23	2023-09-23
COVGCA2001	2023-03-27	2023-09-27
COVGCCF2012	2023-03-22	2023-09-22
COVGCCF2013	2023-03-23	2023-09-23

**Celltrion USA, Inc.: Celltrion DiaTrust COVID-19 Ag Home Test
12-month to 18-month self-life extension granted by the FDA May 20, 2022**

Lot Number	Tests with this printed expiration date (Year-month-day)	Now have this extended expiration date (Year-month-day)
COVSA1001*	2022-11-17	2023-05-17
COVSA1002*	2022-11-19	2023-05-19
COVSA1003* COVSD1001	2022-11-21	2023-05-21
COVSD1002	2022-11-24	2023-05-24
COVSD1003	2022-11-26	2023-05-26
COVSA1004*	2022-11-29	2023-05-29
COVSD1004	2022-11-30	2023-05-30
COVSA1005*	2022-12-01	2023-06-01
COVSA1006*	2022-12-02	2023-06-02
COVSA1007*	2022-12-05	2023-06-05
COVSA1008* COVSD1005	2022-12-07	2023-06-07
COVSA1009*	2022-12-08	2023-06-08
COVSA1010* COVSE1001	2022-12-10	2023-06-10
COVHD1001	2022-12-12	2023-06-12
COVHD1002 COVSA1011*	2022-12-13	2023-06-13
COVSD1006 COVSA1012*	2022-12-15	2023-06-15
COVSA1013* COVSC1001*	2022-12-16	2023-06-16
COVSC1002*	2022-12-19	2023-06-19
COVSA1014*	2022-12-20	2023-06-20
COVSC1003*	2022-12-21	2023-06-21
COVSA1015* COVSD1007	2022-12-22	2023-06-22
COVSC1004*	2022-12-23	2023-06-23

For lot numbers with (*), if your test has this lot number followed by additional letters, the expiration dates listed also apply. For example, a test with lot number COVSA1001, would have the same manufacture date as lot numbers COVSA1001-A or COVSA1001-HF. Lot numbers COVSA1001-A or COVSA1001-HF would have the same extended expiration date as COVSA1001 in the table above.

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Lot Number	Tests with this printed expiration date (Year-month-day)	Now have this extended expiration date (Year-month-day)
COVSB1001* COVSC1005*	2022-12-26	2023-06-26
COVSA1016* COVSB1002* COVSC1006*	2022-12-27	2023-06-27
COVSA1017* COVSB1003* COVSC1007*	2022-12-28	2023-06-28
COVSA1018* COVSB1004* COVSC1008*	2022-12-29	2023-06-29
COVSB1005* COVSC1009*	2022-12-30	2023-06-30
COVSB1006*	2023-01-02	2023-07-02
COVHC2001 COVSA2001* COVSB1007*	2023-01-03	2023-07-03
COVHC2002 COVSA2002* COVSB1008*	2023-01-04	2023-07-04
COVHC2003	2023-01-05	2023-07-05
COVHA2001 COVHC2004 COVSD1008	2023-01-06	2023-07-06
COVHA2002 COVHC2005	2023-01-07	2023-07-07
COVHC2006	2023-01-08	2023-07-08

For lot numbers with (*), if your test has this lot number followed by additional letters, the expiration dates listed also apply. For example, a test with lot number COVSA1001, would have the same manufacture date as lot numbers COVSA1001-A or COVSA1001-HF. Lot numbers COVSA1001-A or COVSA1001-HF would have the same extended expiration date as COVSA1001 in the table above.

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Lot Number	Tests with this printed expiration date (Year-month-day)	Now have this extended expiration date (Year-month-day)
COVHA2003	2023-01-11	2023-07-11
COVHA2004 COVSC2001*	2023-01-13	2023-07-13
COVSA2003*	2023-01-14	2023-07-14
COVSA2004* COVSC2002* COVSP2001*	2023-01-16	2023-07-16
COVSC2003* COVSP2002*	2023-01-17	2023-07-17
COVSA2005* COVSC2004* COVSP2003*	2023-01-18	2023-07-18
COVSP2004*	2023-01-19	2023-07-19
COVSA2006* COVSB2001* COVSC2005* COVSP2005*	2023-01-20	2023-07-20
COVSB2002*	2023-01-21	2023-07-21
COVSB2003*	2023-01-22	2023-07-22
COVSA2007* COVSB2004* COVSC2006*	2023-01-23	2023-07-23

For lot numbers with (*), if your test has this lot number followed by additional letters, the expiration dates listed also apply. For example, a test with lot number COVSA1001, would have the same manufacture date as lot numbers COVSA1001-A or COVSA1001-HF. Lot numbers COVSA1001-A or COVSA1001-HF would have the same extended expiration date as COVSA1001 in the table above.

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Lot Number	Tests with this printed expiration date (Year-month-day)	Now have this extended expiration date (Year-month-day)
COVHE2001 COVSC2007*	2023-01-24	2023-07-24
COVSB2005* COVSC2008*	2023-01-25	2023-07-25
COVHL2001* COVSB2006* COVSC2009*	2023-01-26	2023-07-26
COVSB2007* COVSC2010*	2023-01-27	2023-07-27
COVSB2008* COVSC2011*	2023-02-02	2023-08-02
COVSB2009*	2023-02-03	2023-08-03
COVSB2010* COVSC2012*	2023-02-06	2023-08-06
COVSB2011* COVSC2013*	2023-02-07	2023-08-07
COVSB2012* COVSC2014*	2023-02-08	2023-08-08
COVSB2013* COVSC2015*	2023-02-09	2023-08-09
COVSC2016*	2023-02-10	2023-08-10
COVSC2017*	2023-02-11	2023-08-11
COVSC2018*	2023-02-14	2023-08-14
COVSB2014*	2023-03-10	2023-09-10

For lot numbers with (*), if your test has this lot number followed by additional letters, the expiration dates listed also apply. For example, a test with lot number COVSA1001, would have the same manufacture date as lot numbers COVSA1001-A or COVSA1001-HF. Lot numbers COVSA1001-A or COVSA1001-HF would have the same extended expiration date as COVSA1001 in the table above.

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COVSB2015*	2023-03-11	2023-09-11
COVSB2016*	2023-03-12	2023-09-12
COVSA2008* COVSB2017*	2023-03-13	2023-09-13
COVSA2009*	2023-03-14	2023-09-14
COVSG2001*	2023-03-27	2023-09-27
COVSA2010*	2023-03-31	2023-10-01

For lot numbers with (*), if your test has this lot number followed by additional letters, the expiration dates listed also apply. For example, a test with lot number COVSA1001, would have the same manufacture date as lot numbers COVSA1001-A or COVSA1001-HF. Lot numbers COVSA1001-A or COVSA1001-HF would have the same extended expiration date as COVSA1001 in the table above.