



InteliSwab® COVID-19 Rapid Test Shelf-Life Extension Notification

August 2022

Dear Valued Customer,

Since the launch of the InteliSwab® COVID-19 Rapid Test, InteliSwab® COVID-19 Rapid Test Pro, and InteliSwab® COVID-19 Rapid Test Rx, OraSure has continued to test for product stability to support the extension of the expiration date. We are pleased to announce that on August 3, 2022, **the FDA has extended the product expiration to 12 months.**

This letter is to notify you that the following products may now have a longer than labeled product expiry date:

- InteliSwab® COVID-19 Rapid Test, part number 1001-0622 (UPC: 608337001624) or 1001-0616 (UPC: 608337001581)
- InteliSwab® COVID-19 Rapid Test Pro, part number 1001-0614
- InteliSwab® COVID-19 Rapid Test Rx, part number 1001-0620

A listing of InteliSwab® lot numbers which qualify for this expiry extension can be found in Attachment 1. We are pleased to offer our customers this additional dating in support of their COVID-19 testing efforts. Future extensions will be communicated as more data becomes available.

If you have further questions, please contact Customer Care at the following:

- Telephone: 1-833-601-0127
- Email: customer care@orasure.com

Sincerely,

Tiffany Miller

Vice President, Regulatory and Quality Assurance

This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

**Attachment 1 – IntelliSwab® COVID-19 Rapid Test, IntelliSwab® COVID-19 Rapid Test Pro,
and IntelliSwab® COVID-19 Rapid Test Rx lots with extended expiry**

Kit Lot Number	Original Expiration Date	New 12-Month Expiration Date
6687585, 6687586, 6688526, 6688589, 6688590, 6688591, 6688592, 6688928, 6689224	5/31/2022	8/31/2022
6689248, 6689316, 6689317, 6689318, 6689319, 6699320, 6689321, 6689742, 6689743, 6689744, 6689745, 6689749, 6690059, 6690060, 6690061, 6689225, 6689226, 6689748	6/30/2022	9/30/2022
23210012	7/15/2022	10/15/2022
23210013	7/21/2022	10/21/2022
23210014	7/22/2022	10/22/2022
23210015	7/26/2022	10/26/2022
6690063, 6690068, 6690069, 6690137, 6690393, 6690395, 6690397, 6690398, 6690400, 6690678, 6690850, 6690912, 6691017, 6691018, 6691024, 6691025, 6691026, 6691027, 6691028, 6691110, 6690394, 6690399, 6690851	7/31/2022	10/31/2022
23210035	8/29/2022	11/29/2022
6692103, 6691682, 6692100, 6692192, 6691109, 6691111, 6691112, 6691113, 6691116, 6691243, 6691244, 6691245, 6691246, 6691386, 6691571, 6691595, 6691598, 6691599, 6691600, 6691601, 6691602, 6691679, 6692101, 6692102, 6692104, 6691108, 6691115, 6691384, 6691387, 6691389, 6691677, 6691678, 6691680, 6691681	8/31/2022	11/30/2022
23210037	9/1/2022	12/1/2022
23210038, 23210039, 23210040	9/2/2022	12/2/2022
23210042	9/3/2022	12/3/2022
23210043	9/4/2022	12/4/2022
23210044, 23210045, 23210046, COVAY-1335	9/7/2022	12/7/2022
23210047, 23210048, 23210049, COVAY-1336	9/8/2022	12/8/2022
23210051	9/10/2022	12/10/2022
COVAY-1337	9/11/2022	12/11/2022
COVAY-1338	9/14/2022	12/14/2022
COVAY-1340	9/15/2022	12/15/2022
COVAY-1341, 23210058, 23210057, 23210059	9/16/2022	12/16/2022
COVAY-1342	9/17/2022	12/17/2022
23210060	9/18/2022	12/18/2022
23210061	9/20/2022	12/20/2022
COVAY-1346	9/22/2022	12/22/2022
COVAY-1347	9/23/2022	12/23/2022
23210063	9/24/2022	12/24/2022
23210064	9/27/2022	12/27/2022
23210065	9/28/2022	12/28/2022

6692112, 6692113, 6692194, 6692108, 6692107, 6692106, 6692109, 6692110, 6692111, 6692203, 23210066, 6692198, 6692199, 6692201, 6692202, 6692204, 6692204A, 6692205, 6692105, 6692195, 6692196, 6692200	9/30/2022	12/30/2022
COVAY-2002	10/3/2022	1/3/2023
23220001	10/4/2022	1/4/2023
23220002, COVAY-2004	10/5/2022	1/5/2023
23220003	10/6/2022	1/6/2023
23220005, 23220006	10/10/2022	1/10/2023
23220007	10/11/2022	1/11/2023
COVAY-2007, COVAY-2008	10/13/2022	1/13/2023
23220008, 23220009	10/14/2022	1/14/2023
COVAY-2010, 23220011, 2320010	10/17/2022	1/17/2023
23220013, 23220014, COVAY-2013, COVAY-2014, COVAY-2015	10/20/2022	1/20/2023
23220015	10/21/2022	1/21/2023
23220016, 23220017, COVAY-2017, COVAY-2018	10/24/2022	1/24/2023
23220018	10/25/2022	1/25/2023
23220020, COVAY-2019, COVAY-2020	10/27/2022	1/27/2023
23220021, 23220022	10/28/2022	1/28/2023
6692206, 6692207, 6692208, 6693365, 6693366, 6693367, 6693368, 6693369, 6693370, 6693371, 6693372, 6693373, 6693374, 6693375, 6693880, 6693381, 6693882, 6693883, 6693884, 6693885, 6694040, 6694041, 6694042, 6694043, 6694044, 6694045, 6694261	10/31/2022	1/31/2023
23220025	11/2/2022	2/2/2023
23220027	11/3/2022	2/3/2023
COVAY-2036, COVAY-2038	11/7/2022	2/7/2023
23220030, COVAY-2037	11/8/2022	2/8/2023
COVAY-2041, COVAY-2042	11/10/2022	2/10/2023
COVAY-2043	11/12/2022	2/12/2023
23220042, COVAY-2045	11/14/2022	2/14/2023
23220043, COVAY-2046, COVAY-2047	11/15/2022	2/15/2023
COVAY-2048, COVAY-2049	11/17/2022	2/17/2023
COVAY-2050, COVAY-2051	11/18/2022	2/18/2023
23220044, 23220045, COVAY-2052, COVAY-2053	11/19/2022	2/19/2023
23220048, COVAY-2056	11/22/2022	2/22/2023
COVAY-2057	11/23/2022	2/23/2023
COVAY-2059, COVAY-2060	11/24/2022	2/24/2023
23220052, COVAY-2061, COVAY-2062	11/25/2022	2/25/2023
23220054	11/26/2022	2/26/2023
23220055, 23220056, COVAY-2063	11/28/2022	2/28/2022

6694260, 6694262, 6694263, 6694269, 6694270, 6694271, 6694272, 6694273, 6694274, 6694275, 6694276, 6694277, 6694278, 6694279, 6694702, 6694704, 6694705, 6694706, 6694707, 6694708, 6694709, 6694710, 6694711, 6694712, 6694713, 6694714	11/30/2022	2/28/2023
COVAY-2064	12/1/2022	3/1/2023
23220057, 23220059	12/2/2022	3/2/2023
23220058, 23220060, 23220058A	12/3/2022	3/3/2023
23220066, COVAY-2068	12/4/2022	3/4/2023
23220061, 23220062, 23220063, COVAY-2070	12/5/2022	3/5/2023
23220064, COVAY-2071	12/7/2022	3/7/2023
23220065, COVAY-2072	12/8/2022	3/8/2023
23220067, COVAY-2073	12/9/2022	3/9/2023
23220068	12/10/2022	3/10/2023
23220070, 23220071, COVAY-2074, COVAY-2075	12/11/2022	3/11/2023
23220069, 23220072, COVAY-2076	12/14/2022	3/14/2023
COVAY-2077, COVAY-2078	12/15/2022	3/15/2023
23220073, 23220074	12/16/2022	3/16/2023
23220075, COVAY-2079	12/17/2022	3/17/2023
23220076, COVAY-2080	12/18/2022	3/18/2023
23220077	12/19/2022	3/19/2023
COVAY-2081, COVAY-2082	12/21/2022	3/21/2023
CD220078, CD220079, COVAY-2083	12/22/2022	3/22/2023
CD220082, CD220083	12/24/2022	3/24/2023
CD220084, COVAY-2084, COVAY-2085	12/25/2022	3/25/2023
CD220085, COVAY-2086	12/26/2022	3/26/2023
CD220086	12/28/2022	3/28/2023
CD220088, CD220089	12/30/2022	3/30/2023
6694715, 6694716, 6695115, 6695116, 6695117, 6695118, 6695125, 6695126, 6695127, 6695128, 6695129, 6695130, 6695708, 6695709, 6695710, 6695711, 6695712, 6695713, 6695714, 6695715, 6696076, 6696077, 6696078, CD220090	12/31/2022	3/31/2023
CD220091	1/1/2023	4/1/2023
CD220092, CD220093, COVAY-2091, COVAY-2092	1/2/2023	4/2/2023
COVAY-2093	1/4/2023	4/4/2023
CD220094, CD220095	1/5/2023	4/5/2023
CD220097	1/6/2023	4/6/2023
CD220096	1/7/2023	4/7/2023
CD220098, CD220099, CD220100	1/8/2023	4/8/2023
COVAY-2094	1/9/2023	4/9/2023
CD220101, CD220102, CD220103, COVAY-2095, COVAY-2096, COVAY-2097	1/11/2023	4/11/2023
CD220104, CD220105, CD220106	1/13/2023	4/13/2023
CD220107, CD220108, CD220109	1/14/2023	4/14/2023
CD220110, CD220111	1/16/2023	4/16/2023
CD220112	1/17/2023	4/17/2023

CD220113	1/18/2023	4/18/2023
CD220114, COVAY-2098, COVAY-2099, COVAY-2100	1/19/2023	4/19/2023
CD220115, CD220116, CD220117	1/20/2023	4/20/2023
CD220118, CD220119, COVAY-2101	1/21/2023	4/21/2023
CD220120, CD220121, COVAY-2102, COVAY-2103	1/22/2023	4/22/2023
CD220122, CD220123	1/23/2023	4/23/2023
CD220124	1/24/2023	4/24/2023
CD220125	1/25/2023	4/25/2023
CD220126, CD220127, CD220128, COVAY-2104, COVAY-2105, COVAY-2106	1/26/2023	4/26/2023
CD220129	1/27/2023	4/27/2023
CD220130, CD220131, COVAY-2107	1/28/2023	4/28/2023
CD220132, CD220133	1/29/2023	4/29/2023
CD220134, CD220135, COVAY-2108, COVAY-2109	1/30/2023	4/30/2023
6696079, 6696080, 6696081, 6696082, 6696083, 6696084, 6696085, 6696626, 6696627, 6696628, 6696629, 6696630, 6696928, 6696929, 6696931, 6696932, 6696933, 6696934, 6696935, 6696936	1/31/2023	4/30/2023
COVAY-2121	2/4/2023	5/4/2023
CD220136, CD220137, CD220164, COVAY-2122, COVAY-2123	2/5/2023	5/5/2023
CD220138, CD220139, CD220140	2/6/2023	5/6/2023
CD220141, CD220142, CD220143, CD220144, CD220145, COVAY-2124, COVAY-2125, COVAY-2126	2/7/2023	5/7/2023
CD220146, COVAY-2127, COVAY-2128	2/9/2023	5/9/2023
CD220147, CD220148	2/10/2023	5/10/2023
CD220149, CD220150, CD220151, COVAY-2129, COVAY-2130	2/11/2023	5/11/2023
CD220152, CD220153, CD220154	2/12/2023	5/12/2023
CD220155, COVAY-2131	2/13/2023	5/13/2023
CD220156, CD220157, COVAY-2133	2/14/2023	5/14/2023
CD220158, CD220159, CD220160	2/16/2023	5/16/2023
CD220161, CD220162, COVAY-2134, COVAY-2135	2/17/2023	5/17/2023
CD220163	2/18/2023	5/18/2023
COVAY-2136	2/19/2023	5/19/2023
COVAY-2137	2/20/2023	5/20/2023
COVAY-2138	2/23/2023	5/23/2023
COVAY-2139, COVAY-2140	2/24/2023	5/24/2023
CD220165, CD220166, CD220167	2/25/2023	5/25/2023
CD220168, CD220169, CD220170, COVAY-2141, COVAY-2142, COVAY-2143	2/26/2023	5/26/2023
CD220171	2/27/2023	5/27/2023
6697247, 6697248, 6697249, 6697250, 6697251, 6697252, 6697253, 6697255, 6697549, 6697550, 6697551, 6697552, 6697553, 6697554, 6697555, 6698226, CD220172, CD220173, CD220174, COVAY-2144, COVAY-2145, COVAY-2146	2/28/2023	5/28/2023
CD220175	3/1/2023	6/1/2023

CD220176	3/2/2023	6/2/2023
CD220177	3/3/2023	6/3/2023
CD220178, CD220179, COVAY-2152	3/4/2023	6/4/2023
CD220180, COVAY-2153, COVAY-2154	3/6/2023	6/6/2023
CD220181, CD220182	3/7/2023	6/7/2023
CD220183, COVAY-2155	3/8/2023	6/8/2023
CD220184	3/9/2023	6/9/2023
CD220185, CD220186	3/11/2023	6/11/2023
CD220187, CD220188, CD220189, COVAY-2156, COVAY-2157	3/13/2023	6/13/2023
CD220190, COVAY-2158, COVAY-2159, COVAY-2160	3/14/2023	6/14/2023
CD220191, COVAY-2161	3/16/2023	6/16/2023
CD220192, CD220193, CD220194	3/17/2023	6/17/2023
CD220195, CD220196	3/20/2023	6/20/2023
CD220197, CD220198, COVAY-2163, COVAY-2162	3/21/2023	6/21/2023
CD220199	3/22/2023	6/22/2023
CD220200, COVAY-2164	3/24/2023	6/24/2023
CD220201, CD220202, CD220203	3/25/2023	6/25/2023
CD220204	3/27/2023	6/27/2023
COVAY-2165	3/28/2023	6/28/2023
CD220205, CD220206, COVAY-2166	3/29/2023	6/29/2023
CD220207, CD220208	3/30/2023	6/30/2023
6697556, 6697557, 6697558, 6697559, 6697560, 6697561, 6698698, 6698699, 6698700, 6698702, 6698704	3/31/2023	6/30/2023
CD220209, COVAY-2182	4/2/2023	7/2/2023
CD220210	4/4/2023	7/4/2023
CD220211, CD220212, COVAY-2183	4/5/2023	7/5/2023
CD220213, COVAY-2184	4/6/2023	7/6/2023
CD220214	4/7/2023	7/7/2023
CD220215, CD220216	4/8/2023	7/8/2023
CD220217	4/9/2023	7/9/2023
CD220218, COVAY-2185	4/11/2023	7/11/2023
COVAY-2186	4/12/2023	7/12/2023
COVAY-2187	4/13/2023	7/13/2023
CD220219, CD220220, CD220221	4/14/2023	7/14/2023
CD220222	4/15/2023	7/15/2023
CD220223	4/16/2023	7/16/2023
CD220226	4/18/2023	7/18/2023
CD220224, CD220225, COVAY-2188, COVAY-2189	4/19/2023	7/19/2023
CD220228, COVAY-2190	4/20/2023	7/20/2023
CD220230, CD220231, CD220232	4/21/2023	7/21/2023
CD220234, CD220235, CD220236, CD220237	4/23/2023	7/23/2023
CD2200239	4/25/2023	7/25/2023
COVAY-2191, CD2200238, CD2200240, CD2200241	4/26/2023	7/26/2023
CD2200242, CD2200243	4/27/2023	7/27/2023
COVAY-2192, CD2200244, CD2200245, CD2200246	4/29/2023	7/29/2023

6698703, 6698945, 6698946, 6698947, 6698948, 6698949, 6698950, COVAY-2193, COVAY-2194, COVAY-2195, CD2200247	4/30/2023	7/30/2023
COVAY-2213, CD2200250	5/1/2023	8/1/2023
COVAY-2214, COVAY-2215	5/2/2023	8/2/2023
COVAY-2216, CD2200248, CD2200249	5/3/2023	8/3/2023
CD2200251	5/4/2023	8/4/2023
CD2200252	5/5/2023	8/5/2023
CD2200253	5/6/2023	8/6/2023