STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Public Health Preparedness and Local Health Section

DATE: August 5, 2022 OPHPR-2022-011

TO: CT DPH Stakeholders and Entities

FROM: Francesca Provenzano, MPH, RS, Chief
Public Health Preparedness and Local Health Section

RE: iHealth Test Kit Extension

On July 5, 2022, the manufacturer of iHealth COVID-19 antigen rapid test kits announced that they had received approval through the Food and Drug Administration (FDA) to extend the expiration date on their test kits for an additional three-months. This second FDA approval extends the shelf-life for all iHealth tests to **six months past the labeled expiration date on the box**. For example, if the expiration date printed on your test kit box reads 2022-08, the updated expiration date is 2023-02.

iHealth Test Kit instructions are available in multiple languages including Albanian, Arabic, Chinese, English, French, Haitian Creole, Japanese, Khmer, Polish, Portuguese, Russian, Spanish, and Vietnamese. Please visit the links below to view the FDA letter and look up the new expiration date.

Also, attached to this memorandum is guidance issued by the Connecticut Department of Energy and Environmental Protection related to appropriate disposal of rapid antigen test kits, in the event your existing supplies of iHealth test kits (or other test kit brands) have gone beyond their **extended** expiration date. Always check with the manufacturer before discarding your test kits, as they have likely received FDA approval for a shelf-life extension.

If you have any questions, or would like to obtain alternative language instructions, please submit an email to PHAD.dph@ct.gov.

c: Ellen Blaschinski, MBA, RS, Branch Chief

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Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Phone: (860) 509-8282 • Fax: (860) 509-7160
Telecommunications Relay Service 7-1-1
410 Capitol Avenue, P.O. Box 340308 MS#13PHP
Hartford, Connecticut 06134-0308
www.ct.gov/dph
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List of COVID-19 Antigen Rapid Test Kits And Disposal Information

Note: Test kits shaded in yellow denote those which have been identified as being purchased and/or distributed by the State of Connecticut.

Prepared by Ross Bunnell Revised 7/26/2022

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
Abbott BinaxNOW	No ingredients listed in MSDS. Says it contains no OSHA-regulated substances. Flash point "NA." No pH data. Disposal section says "Dispose of contents/container in accordance with licensed collector's sorting instructions." The Healthcare Provider Instructions indicate just one non-hazardous ingredient – sodium azide (0.0125%).[1] This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	MSDS: https://nhfa-ems.com/wp-content/uploads/2020/11/BinaxNOW-COVID-19-Device-SDS-US-195-.pdf. There is also ingredient information on page 3 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/144575/download.
AccessBio CareStart COVID-19 Antigen Home Test	The MSDS I did find (which does not appear to be the right one) only lists one hazardous ingredient – sodium azide.[1] The Healthcare Provider Instructions list the ingredients as sodium tetraborate (a buffer), EDTA (a preservative), sodium chloride, Triton X-100 (a detergent), and N-Lauroylsarcosine sodium salt (a surfactant) – none of which are hazardous waste constituents. No pH or flash point data is provided. This product appears not to be a HW, but I would need to get the correct MSDS to confirm.	The only MSDS I can find on the website appears to be for the antigen test kit to be used by medical practitioners, not for home use: http://s878047141.onlinehome.us/wp-content/uploads/2021/09/MSDS16-RCH-B-C19-Ag-2021-04-13F.pdf. There is ingredient information on page 6 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/151248/download.
ACONlab FlowFlex	No ingredients are listed in MSDS. Says it contains no OSHA-regulated substances. Flash point "NA." No pH data. Disposal section says "Dispose of contents/container in accordance with	MSDS: https://www.germainelabs.com/wp-content/uploads/2021/11/Flowflex-Covid-19-Antigen-Home-Test-Safety-Data-Sheet-1.pdf. There is also ingredient information on page 3 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/152698/download.

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
	licensed collector's sorting instructions." Healthcare Provider Instructions list two ingredients – TX-100, 1% (a surfactant) and sodium azide, 0.02%, neither of which are hazardous waste constituents.[1] This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	
Becton Dickinson BD Veritor	Sodium azide 0.0946% is the only ingredient listed.[1] Flash point and pH both say "no data." Disposal section says "Dispose of waste and residues in accordance with local authority requirements." The Healthcare Provider Instructions indicate the extraction fluid is a detergent solution with 0.1% sodium azide.[1] This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	MSDS: https://www.medline.com/media/catalog/Docs/MSDS/MSD_SDSD714539.pdf. There is also ingredient information on page 5 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/151761/download.
Celltrion DiaTrust COVID-19 Ag Home Test	The Healthcare Provider Instructions from the FDA website indicate that the "extraction buffer" contains 0.09% sodium azide.[1] This product appears not to be a HW, but I would need to get an MSDS to confirm.	I could not find an MSDS on the company website, https://www.celltrion.com/en-us/home/index. However, there is ingredient information on page 5 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/153419/download.
Cue Health Inc.. Covid-19 Test for Home and OTC Use	Insufficient information.	I could not find an MSDS on the company website, https://cuehealth.com/. There are no Healthcare Provider Instructions on the FDA website. However, there are user instructions available on the company website (as a download only), but these instructions contain no ingredient information.
Detect, Inc. Covid-19 Test	Insufficient information.	I could not find an MSDS on the company website, https://detect.com/. There are no Healthcare Provider Instructions on the FDA website. However, the FDA website does have user instructions at

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
		https://www.fda.gov/media/153746/download, but these instructions contain no ingredient information.
Ellume Limited Covid-19 Home Test	The Healthcare Provider Instructions indicate that the "processing fluid" contains ProClin 300 (a biocide) at 0.002 – 0.005%. This product appears not to be a HW, but I would need an MSDS to confirm.	I could not find an MSDS on the company website, https://www.ellumehealth.com/. However, there is ingredient information on page 3 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/144592/download.
GenBody	Contains sodium azide < 0.09%.[1] Also, 4 other non-hazardous-waste constituents: sodium carbonate, sodium bicarbonate, a detergent, and disodium EDTA. No flash point data; pH is "neutral." Disposal Section says "Waste must be disposed of in accordance with federal, state and local environmental control regulations." This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	MSDS: https://www.meridianbioscience.com/uploads/MSDS_GB-TCF-104-05_rev1.1_Specification-of-materials_09.24.21.pdf.
iHealth	The Healthcare Provider Instructions say the extraction reagent contains Triton X-100 (a detergent) and ProClin 300 (a biocide), neither of which are hazardous waste constituents. The MSDS also lists sodium phosphate monobasic monohydrate, sodium phosphate dibasic, sodium chloride, and tetrasodium EDTA, all at 1% or less each. No specific pH or flash point data, but based on the ingredients, it should not be hazardous for either one. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	I can't find an MSDS on the company website, https://ihealthlabs.com, but I received a copy from the manufacturer. There is also hazardous ingredient information on page 6 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/153923/download.

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
InBios SCoV-2 Ag Detect Rapid Self-Test	The Healthcare Provider Instructions from the FDA website indicate that the test kit contains IGEPAL CA-630 and ProClin 300 (a surfactant, and a biocide, respectively). Both are not HW constituents. However, there is no pH or flash point data. This product appears not to be a HW, but an MSDS would be needed to confirm this.	I can't find an MSDS on the company website, https://inbios.com. However, there is hazardous ingredient information on page 3 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/154336/download.
Lucira CHECK IT COVID-19 Test Kit	Insufficient information.	I can't find an MSDS on the company website, https://checkit.lucirahealth.com.
MaximBio ClearDetect COVID-19 Antigen Home Test	The Healthcare Provider Instructions indicate that the following ingredients: Microcide III at 0.2% (a biocide), TRIS Base at 0.242% (a buffer), Tris-HCl at 0.314% (another buffer), sodium chloride at 1.75%, and NP-40 at 0.6% (a surfactant), none of which are hazardous waste constituents. However, there is no pH or flash point data. This product appears not to be a HW, but an MSDS would be needed to confirm this.	I can't find an MSDS on the company website, www.maximbio.com. However, there is ingredient information on page 7 of the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/155634/download.
Nano-Ditech Nano-Check	Only ingredient listed is sodium azide at <0.1%.[1] No pH or flash point data. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	MSDS: https://www.nanoditech.com/pdf/MSDS.pdf.
On/Go	The Healthcare Provider Instructions indicate that the solution contains sodium tetraborate pentahydrate (Borax), ethylene diamine tetra-acetic acid (EDTA), sodium chloride, Triton X-100 (a detergent), and N-lauroylsarcosine sodium salt (another detergent). No pH or flash point data. This product appears	I can't find an MSDS on the company website, https://www.letsongo.com. However, there is ingredient information on page 4 of the Healthcare Provider Instructions: https://assets-global.website-files.com/60afb5920d611dc2eeaef451/619d515f95a3f170e221ffe4_IFU-RCPM79-E%20(B)%20IFU%20(ongo)%202021-11-22F.pdf. I requested an MSDS be sent to me, and they sent me the MSDS for the cassette only. I emailed back asking for the MSDS for the extraction fluid but have not yet received a response.

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
	not to be a HW, but I am awaiting MSDS to be sent to me to confirm.	
OraSure InteliSwab COVID-19 Rapid Test	Insufficient information.	I can't find an MSDS on the company website, https://inteliswab.com. There are Healthcare Provider Instructions on the FDA website at https://www.fda.gov/media/149911/download, but these do not include an ingredient list.
Ortho Clinical Diagnostics VITROS	Insufficient information.	I can't find an MSDS on the company website, www.orthoclinicaldiagnostics.com.
OSANG LLC OHC COVID-19 Antigen Self Test	The Healthcare Provider Instructions list sodium azide[1] at 0.05%, Triton X-100 (a detergent) at 1%, BIS (trimethysilylacetamide) (function unknown) at 1.0%, and Tris(hydroxymethyl) Aminoethane (a buffer) at 1.2 %. However, there is no pH or flash point data. This product appears not to be a HW, but I would need an MSDS to confirm.	I can't find an MSDS on the company website, https://www.osanghc.com/en/home_en/. However, there is ingredient information in the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/157548/download.
Phase Scientific INDICAID COVID-19 Rapid Antigen At-Home Test	MSDS lists <0.05% each of two non-hazardous constituents – Triton X-100 and ProClin 300 (a detergent and a biocide, respectively). No flash point data; pH = 7.2. Disposal section says "Dispose in accordance with all applicable local and national regulations." This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	MSDS: https://us.phasescientific.com/wp-content/uploads/2021/08/SDS-0031-B-INDICAID-COVID-19-Rapid-Antigen-Test-SDS_Current.pdf. There is also ingredient information in the Healthcare Provider Instructions on the FDA website at: https://www.fda.gov/media/156954/download which includes a hazardous ingredients list that indicates the same ingredients as listed in the MSDS.
Quanterix Simoa	Contains several non-hazardous constituents at less than 0.1% - bovine serum albumin (a blocking reagent), a mixture of 5-chloro-2-methy-3(2H)-isothiazolone and 2-methyl-3(2H)-	MSDS: https://www.quanterix.com/wp-content/uploads/2021/01/SARS-CoV-2-N-Protein-Antigen-Kit-Bead-SDS-103789.pdf

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
	isothiazolone (a biocide), and other "non-hazardous proprietary ingredients." No flash point data; pH = 6-9. Disposal section basically says to dispose of in accordance with applicable requirements. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	
Quidel QuickVue At-Home OTC COVID-19 Test	Solution contains less than 1% each of sodium phosphate monobasic monohydrate (a buffer), sodium phosphate dibasic (another buffer), C12-14 Alkyldimethyl-betaines (an emulsifier), ProClin 300 (a biocide), and Tetrasodium EDTA (a preservative), all of which are non-hazardous. pH is 6.8. No Flash point data. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	They have hazardous ingredient information on page 4 of the Healthcare Provider Instructions on the FDA website: https://www.fda.gov/media/147265/download. The MSDS was sent to me separately by the company, from which I got the pH value.
Salofa Oy Sienna-Clarity	The Instructions for Use indicate that there are two ingredients: Tris (a buffer), and Proclin 300 (a biocide). No pH or flash point data. This product appears not to be a HW, but I would need an MSDS to confirm.	I can't an MSDS on the company website, https://www.salofa.com/. However, there is ingredient information on page 2 of the Instructions for Use on the FDA website at: https://www.fda.gov/media/149055/download.
SD Biosensor, Inc. Pilot COVID-19 At-Home Test	The Healthcare Provider Instructions list four ingredients: sodium chloride, L-Arginine (an amino acid), Polidocanol (a local anesthetic and antipruritic), and ProClin 300 (a biocide). No pH or flash point data. This product appears not to be a HW, but I would need an MSDS to confirm.	I can't find an MSDS on the company website, https://www.sdbiosensor.com. However, there is hazardous ingredient information on page 5 of the Healthcare Provider Instructions on the FDA website: https://www.fda.gov/media/155125/download.

Product Name	Is it a Hazardous Waste?	Web Address for MSDS and/or Other Information on Ingredients
Siemens Healthineers CLINITEST Rapid COVID-19 Antigen Self-Test	The MSDS indicates sodium azide[1] at 0.05% as the only hazardous ingredient. The Healthcare Provider Instructions indicate two ingredients in the extraction fluid – sodium azide[1] at 0.5%, and Triton (a detergent) at 1.5%. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	I found an MSDS on the company website, https://doclib.siemens-healthineers.com/. There is also is ingredient information on page 8 of the Healthcare Provider Instructions on the FDA website: https://www.fda.gov/media/155175/download.
Xiamen Boson Biotech Co., Ltd. Rapid SARS-CoV-2 Antigen Test Card	Healthcare Provider Instructions indicate two ingredients – sodium chloride and Tergitol 15-S-9 (a surfactant), both a 1%. This product appears not to be a HW. However, it would have to be disposed of either as a CT-Regulated Waste (CR04) or a special waste.[2]	I could not find an MSDS on the company website, https://www.bosonbio.com. However, there is hazardous ingredient information on page 8 of the Healthcare Provider Instructions on the FDA website: https://www.fda.gov/media/157544/download.

Footnotes:

1. Sodium azide is listed as hazardous commercial chemical product with the EPA waste code P105. However, a product containing sodium azide is only a hazardous waste under this listing if sodium azide is the "sole active ingredient" in the product being dispose of. Not only do these test kits all include other active ingredients, such as surfactants and buffers, sodium azide is not really even an "active ingredient" in these test kits. It is present in very low concentrations solely as a preservative, and EPA has determined that preservatives are not "active ingredients." As a result, the P105 hazardous waste code does not apply to these test kits.
2. For information on the proper disposal of Connecticut-Regulated Wastes, see the DEEP's Connecticut Regulated Waste webpage. Connecticut-Regulated Wastes must be transported off-site by a DEEP-licensed waste transporter. If a health care facility has a licensed hauler for biomedical waste, it is possible that this hauler may also be permitted to transport Connecticut-Regulated Waste. Special wastes may currently be accepted by four of Connecticut's Resource Recovery Facilities that have DEEP-approved "Special Waste Plans," under the category of "Pharmaceutical Wastes (Pre-Consumer)" and/or "Commodity Wastes (Consumer Products)." The four RRFs that have approved Special Waste Plans include Bridgeport, Bristol, Lisbon, and Preston. However, approval must be obtained from one of these RRFs prior to sending waste for burning at their facility, and special tipping fees and other charges may apply.

Additional Notes:

- For information on the proper management and disposal of Connecticut-Regulated Wastes, see the DEEP Website.

- FDA webpage that lists the Antigen Diagnostic Tests for SARS-CoV-2 for which FDA has issued EUAs: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2
- FDA webpage that lists the approved at-home OTC COVID-19 diagnostic tests: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests