



Abbott Diagnostics
Scarborough, Inc.
10 Southgate Road
Scarborough, ME
04074

BinaxNOW™ COVID-19 Antigen Kits and Expiration dating

BinaxNOW™ COVID-19 Antigen test kits contain components with individual lot numbers and expiration dates. When the components are combined into a kit, the kit is given its own unique lot and expiration date. The components must all have the same or a longer expiration date than the kit to ensure kit performance of the kit as a whole, through expiry.

Kit Expiration Date

Kit expiration dates are identified on the kit box label next to a symbol of an hourglass.

Date of Manufacture

Expiration dates of components are based on the established performance data from the date of manufacture (DOM) of the component itself. The DOM listed on the kit box, is that date the components were packaged into the kit.

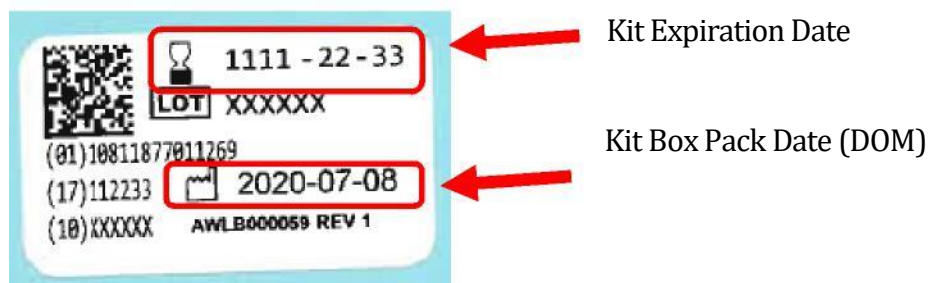
Symbols Key



(hourglass) – Kit Expiration



(empty house) – Kit Box Pack Date (DOM)



Kit Expiration Date

Kit Box Pack Date (DOM)

“Short Dated” Kits

Due to the current demand for COVID-19 kits, some older individual components are being used which “Short date” the kit expiration date.

In EXAMPLE 1 below for 195-000 Kit lot 163449, the expiration date of 2022-01-03, was set by the Positive control swab.

In order to maintain the same kit expiration date across the entire core lot, the components in some kit sub-lots may appear to all have longer expiration dates than the kit. See EXAMPLE 2. The same device lot is used within a core lot, but multiple lots of other components may be used. In EXAMPLE 2 below for 195-260 Kit a different lot of a component was used in another subplot which set the expiration date.

As stated in the package insert under Storage and Stability, the BinaxNOW™ COVID-19 Antigen test kits and components are stable until the expiration dates marked on their outer packaging and containers. Do not use the kit beyond its labeled expiration date.

EXAMPLE 1



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CERTIFICATE OF ANALYSIS

| | | | |
|--------------------------------|--------------------------------------|--|--|
| Product: | BinaxNOW™ COVID-19 Ag Card | | |
| Date(s) of Manufacture: | 2021-10-11 – 2021-10-16 | | |
| Manufactured by: | Abbott Diagnostics Scarborough, Inc. | | |
| Product Number: | 195-000 | | |
| Lot Number: | 163449 | | |
| Expiration: | 2022-01-03 | | |

| | | | |
|------------------------|--------------|--|-------------------|
| Kit Components: | | | |
| <u>Component</u> | <u>Lot #</u> | | <u>Expiration</u> |
| Devices | 155710 | | 2022-04-13 |
| Extraction Reagent | 148622 | | 2022-01-08 |
| Positive Control Swab | 150994 | | 2022-01-03 |
| Patient Swab | 2021030033 | | 2023/03/09 |

| | | |
|-------------------------|----------------------------|----------------|
| Kit Performance: | | |
| <u>Sample ID</u> | <u>Acceptance Criteria</u> | <u>Results</u> |
| Positive QC Samples | Positive | Pass |
| Negative QC Samples | Negative | Pass |

Conforms to specifications.

EXAMPLE 2

|  Abbott | Abbott Diagnostics Scarborough, Inc. 10 Southgate Road Scarborough, ME 04074 USA T: +1 207.730.5750 F: +1 207.730.5717 | | | | | | | | | | | | |
|--|--|-------------------|--------------|-------------------|--------|--------|------------|----------------------------|--------|------------|--------------|-------|------------|
| CERTIFICATE OF ANALYSIS | | | | | | | | | | | | | |
| Product: | BinaxNOW™ COVID-19 Antigen Self Test | | | | | | | | | | | | |
| Date(s) of Manufacture: | 2021-10-11 | | | | | | | | | | | | |
| Manufactured by: | Abbott Diagnostics Scarborough, Inc. | | | | | | | | | | | | |
| Product Number: | 195-160 / 195-260 | | | | | | | | | | | | |
| Lot Number: | 166948 / 166948B | | | | | | | | | | | | |
| Expiration: | 2022-03-26 | | | | | | | | | | | | |
| Kit Components: | | | | | | | | | | | | | |
| <table border="1"><thead><tr><th><u>Component</u></th><th><u>Lot #</u></th><th><u>Expiration</u></th></tr></thead><tbody><tr><td>Device</td><td>155918</td><td>2022-04-16</td></tr><tr><td>Extraction Reagent Ampoule</td><td>126141</td><td>2022-04-09</td></tr><tr><td>Patient Swab</td><td>P0327</td><td>2026-04-01</td></tr></tbody></table> | | <u>Component</u> | <u>Lot #</u> | <u>Expiration</u> | Device | 155918 | 2022-04-16 | Extraction Reagent Ampoule | 126141 | 2022-04-09 | Patient Swab | P0327 | 2026-04-01 |
| <u>Component</u> | <u>Lot #</u> | <u>Expiration</u> | | | | | | | | | | | |
| Device | 155918 | 2022-04-16 | | | | | | | | | | | |
| Extraction Reagent Ampoule | 126141 | 2022-04-09 | | | | | | | | | | | |
| Patient Swab | P0327 | 2026-04-01 | | | | | | | | | | | |
| Kit Performance: | | | | | | | | | | | | | |
| <u>Sample ID</u> | <u>Acceptance Criteria</u> | <u>Results</u> | | | | | | | | | | | |
| Positive QC Samples | Positive | Pass | | | | | | | | | | | |
| Negative QC Samples | Negative | Pass | | | | | | | | | | | |
| Conforms to specifications. | | | | | | | | | | | | | |

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