BinaxNOW FAQ'S/CLIA Application Information

BinaxNOW FAQ's

Where can I request BinaxNOW testing supplies?

BinaxNOW COVID-19 Rapid Antigen Test supplies may be requested without cost to the facility from the NH Department of Health and Human Services at the following link: https://prd.blogs.nh.gov/dos/hsem/?page_id=10564.

How do I report results?

All test results are required to be reported to the NH Division of Public Health Services as described in Health Alert Network message #22 available at: https://www.dhhs.nh.gov/dphs/cdcs/alerts/documents/covid-19-update22.pdf

Where do I report results?

A secure web-based reporting portal for point of care COVID-19 tests has been created and is available here: https://forms.nh.gov/EpiInfoWebSurvey/Home/37a7bc1e-69b9-4227-9b36-95d340277229

I need to train my staff on BinaxNOW.

For information and training materials for the BinaxNow, please refer to this website: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Emergency Use Authorization Information

The BinaxNOW COVID-19 Rapid Antigen Test is authorized under a FDA emergency use authorization for testing persons with symptoms of COVID-19. The test requires no additional machine or supplies other than personal protective equipment. Each box comes with 40 tests, each with a nasal swab for the anterior nares, and one dropper bottle of reagent per box. Further information is available at: https://www.fda.gov/media/141570/download

How to obtain a CLIA certification

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA.

All applicable sections in application must be completed. Incomplete applications cannot be processed and will be returned.

Complete instructions for application competition may be found in the CLIA application packet.

Please submit your completed application to CLIA@dhhs.nh.gov.