



# COVID-19 Testing Expansion with BinaxNOW for Oklahoma

Updated November 4, 2020

Testing plays a key role in mitigating the spread of this novel virus and will help to minimize disruptions to school communities across Oklahoma. The Oklahoma State Department of Health (OSDH) is offering optional COVID-19 testing opportunities for teachers and staff at Oklahoma K-12 public schools offering in person instruction.

The BinaxNOW Ag Rapid Card Antigen test will be made available to all Oklahoma K-12 schools at no cost for as long as they remain available. The [BinaxNOW COVID-19 Ag Card](#) is a rapid antigen test designed to detect active infections of COVID-19. This test detects viral proteins (antigens) and is different from the regular molecular or PCR test that detects viral RNA or genome. It has received Emergency Use Authorization from the FDA as a “waived” test, meaning that it is very simple in its design and can be performed by individuals receiving minimum training who follow the manufacturer’s instructions for use.

The 3-step process described below will allow you to begin using the BinaxNOW Ag Card test to test teachers and staff for COVID-19.

## Oklahoma’s 3 Step Process for IHEs

1. CLIA Waiver Application or Revision to Current Certificate



2. Order BinaxNOW Ag Card Kits and Other Supplies



3. Specimen Collection and Reporting Test Results

1. Apply for a CLIA Waiver Certificate or Revise Current Certificate	
A.	<p>First, all testing sites need to either seek their own CLIA Waiver Certificate OR work with a covered entity to administer the tests to students. A CLIA number associated with the certificate is needed to order the BinaxNOW Ag Card test kits.</p> <p>To apply for a new CLIA Waiver Certificate or to revise a current CLIA certificate (i.e., add the BinaxNOW Ag Card test), visit: <a href="https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf">https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf</a></p> <p>For help regarding your CLIA application, contact OSDH Medical Facilities at: Email: <a href="mailto:medicalfacilities@health.ok.gov">medicalfacilities@health.ok.gov</a> Phone: (405)271-6576</p>
B.	<p>Next, the primary person who will be performing or providing oversight of BinaxNOW Ag Card testing should review all training materials available on the <b>BinaxNOW Self-guided Training Website</b> at: <a href="http://globalpointofcare.abbott/navica-binax-training">globalpointofcare.abbott/navica-binax-training</a></p>

## 2. Order BinaxNOW Collection Kits



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A.	<p>To order BinaxNOW Ag Card kits and supplies you will need to set up a user account for the OSDH Emergency PPE Supply Program by completing the Contact Us Form on <a href="#">this page</a>. Once your account is established, you will place orders for at: <a href="https://okppe.mybigcommerce.com/">https://okppe.mybigcommerce.com/</a></p> <p>The BinaxNOW kits are sent in boxes of 40 test kits. You will be able to order BinaxNOW Ag Card test kits at the Big Commerce website at any time as supplies remain available.</p>
B.	<p>Additional information you will need to place your order:</p> <ul style="list-style-type: none"> <li>• <b>Point of Contact Name, School Name, Shipping Address, Collection Site</b> (i.e., the location where specimen will be collected).</li> <li>• <b>CLIA NUMBER</b> - approved for the BinaxNOW antigen testing</li> <li>• Enter the words <b>'SCHOOL TESTING'</b> in the box requesting the "three vendors unable to provide".</li> </ul>

### 3. Specimen Collection and Data Submission Requirements

A.	<p>Sites may begin testing using the BinaxNOW Ag Card as soon as they have an approved CLIA number and staff are trained to collect specimens and report results. All sites using the BinaxNOW antigen test kits will be required to report results.</p> <p>Review instructions for <a href="#">reporting COVID-19 testing to the OSDH Acute Disease Services</a>.</p> <p>Additionally, the Governor's Fourth Amended Executive Order 2020-20, requires all facilities performing COVID-19 testing to report their data daily by 10:00 am using the OSDH <b>COVID-19 Testing Questionnaire</b> at: <a href="https://osdhphs.co1.qualtrics.com/jfe/form/SV_0eLFfFyfLEEbS1">https://osdhphs.co1.qualtrics.com/jfe/form/SV_0eLFfFyfLEEbS1</a></p>	<p>If you have questions that are not covered by the <a href="#">BinaxNOW FAQ</a>, please contact:</p> <p>Natalie Marek  Email: <a href="mailto:Natalie.Marek@health.ok.gov">Natalie.Marek@health.ok.gov</a>  Phone: (405) 271-4200 x52546</p>
B.	<p><b>Designated Point of Contact (POC)</b> will need to assist in the sample collection to assure test workflow is followed. Training videos are available at: <a href="https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html">https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html</a></p> <p>Reporting of all COVID-19 results is required.</p> <p>The person collecting the specimen should don proper PPE (gloves, facial mask or full-faced mask, and a gown or lab coat. Sites should use bleach or alcohol for disinfection (e.g., should a swab be dropped on furniture or a bench, or for cleaning any full-face masks). Supply bags are suitable for waste disposal.</p>	
<p><b>4. Follow-up Confirmatory Testing – if needed</b></p>		



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	<p><b>In certain circumstances, you may need to take a secondary sample for PCR follow-up testing. These instances include:</b></p> <ul style="list-style-type: none"><li>• If you receive a positive result from the BinaxNOW antigen test it is recommended to undergo a PCR test within 24 hours to confirm positive result.</li><li>• OSDH is providing saliva test kits and instruction below to send a saliva sample for processing within 24 hours for those that have a positive result.</li><li>• While you are awaiting the confirmation, people that test positive should follow isolation protocols.</li></ul>
	<p>Instructions for saliva testing and sample processing are as follows:</p> <p><b>1. Prior to specimen collection:</b></p> <ul style="list-style-type: none"><li>▪ Email the following to <a href="mailto:covid19testing@okstate.edu">covid19testing@okstate.edu</a><ul style="list-style-type: none"><li>• Facility (Account) Name</li><li>• Address</li><li>• Phone</li><li>• Fax</li><li>• Email of the administrator of the tests that is authorized to receive results, not the person being tested.</li></ul></li><li>▪ Watch the portal training video <a href="#">here</a></li></ul>
	<p><b>2. What to expect next:</b></p> <ul style="list-style-type: none"><li>▪ Once the information is received, you will have an account set up within our lab and will receive an invitation via email to the ordering portal.<ul style="list-style-type: none"><li>• The invitation will come from <a href="mailto:no-reply@covidtestorder.com">no-reply@covidtestorder.com</a> with the subject line <i>"Invitation Instructions."</i></li><li>• You will need to print requisitions on the paper provided with the saliva kits.</li><li>• <a href="#">SPECIMEN COLLECTION VIDEO</a></li><li>• Mail all specimens via UPS or FedEx – <b>Category B</b> Shipping to:<ul style="list-style-type: none"><li>○ OSU Diagnostic Laboratory 1110 S. Innovation Way Suite 236 Stillwater, OK 74074</li></ul></li></ul></li><li>▪ Results will be sent via encrypted email to the email address provided during account set up.</li><li>▪ It will be <b><u>up to each facility to develop their own deployment plan for providing results to the individuals being tested.</u></b> Confirmed positives will have a follow up case investigation.</li></ul>