

Directions for Clia Certificate of Waiver

- All customers administering **any** Covid Antigen test must have a Clia Certificate of Waiver.
- All customers must also contact their **State Agency** to confirm there are no additional application forms to be completed from appropriate State Agency.
- A State Agency list is provided at the link below in Step 4, for contact information for appropriate states.
- **Information on What a CLIA Certificate of Waiver is:** <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>
- **ADA recommends applying for CLIA Certificate of waiver:** [ADA Recommendation for Covid Testing](#)

HAVING A CLIA CERTIFICATE OF WAIVER WILL GIVE FLEXIBILITY TO DENTAL OFFICES TO PROVIDE TESTING NOW AND IN THE FUTURE. CLIA WAIVER IS THE LOWEST LEVEL FOR TESTING AND MOST APPROPRIATE FOR PRIVATE DENTAL PRACTICES.

A Clinical Laboratory Improvement Amendment (**CLIA**) Certificate of **Waiver** is a **certification** that allows a facility, primarily laboratories, to legally examine a person through **waived** tests in order to assess health, diagnose, and determine treatment. As defined by **CLIA**, **waived** tests are simple tests with a low risk for an incorrect result. They include: Certain tests listed in the **CLIA** regulations. Tests cleared by the FDA for home use.

The Certificate of Waiver is valid for two years. A renewal application will need to be completed and sent to the state agency not less than 9 months before the certificate's expiration date.

The fee for a Certificate of Waiver is \$180.

STEPS:

1. Contact State Agency to find out what requirements are needed by your respective state.
 - a. Tell the State Agency you are applying for a Clia Certificate of Waiver and ask if there are any additional state specific forms required.
2. Fill out any state forms required by respective state.
3. Fill out CMS-116- **Clia Certificate of Waiver**.
4. Submit CMS-116 form to appropriate State Agency (<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>)
5. All questions for completing the CMS-116 form can be answered by appropriate State Agencies.
6. Do not send money with your application.
7. Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee.
8. For additional information or assistance in filling out the CLIA Certificate of Waiver application, call CMS Toll-Free: 877-267-2323.

HELPFUL TIPS FOR COMPLETING THE CMS-116 FORM:

- Section I. Check box in Initial Application, fill this section out in its entirety.
- Section II. Check Certificate of Waiver (complete sections I-VI and IX-X).
- Section III. Most locations will choose option #22 Practitioner Other and enter Independent Dental Practitioner. Community Health Centers- choose appropriate option.
- Section IV. Enter hours in which the facility plans do testing.
- Section V. Choose appropriate selection, if choosing yes, answer remainder of section.
- Section VI. Enter Rapid Antigen Covid Test Enter total estimated Annual test.
- Section VII. Not Required.
- Section VIII. Not Required.
- Section IX. Choose appropriate ownership type.
- Section X. As needed.
- Sign documentation and submit to Local State Agency.

*** Benco Dental will not be held responsible for customers who do not have a Clia Waiver Certificate or who have fill out any forms incorrectly. ***

Dental procedure (CDT) coding for antigen, and antibody, testing CDT Code version (CDT 2021) that is effective January 1, 2021 contains the following new procedure code entries in the Tests and Examinations subcategory within the Diagnostic category of service. Please note that these entries consist of the code and nomenclature; there is no descriptor for either one.

- **D0604 antigen testing for a public health related pathogen, including coronavirus.**
- **D0605 antibody testing for a public health related pathogen, including coronavirus.**

ANY ADDITIONAL QUESTIONS CONCERNING THESE OR OTHER PROCEDURE CODES MAY BE DIRECTED TO DENTALCODE@ADA.ORG.