

California Prenatal Screening Program

Additional Information For Providers About California State-Contracted cfDNA Laboratories

PerkinElmer

1. Methodology for cfDNA analysis?

Unique target fragments on the chromosomes of interest are isolated and incorporated into probes designed specifically for each of these fragments. An innovative process called rolling circle replication amplifies the fragment to make a long chain with thousands of copies of the original targeted fragment. A specific colored fluorescent probe that is unique to a given chromosome binds to this chain. These chains then collapse into small DNA objects that are placed in a powerful imager that then counts the number of fluorescent objects. By comparing ratios of the DNA objects, software can then determine whether there is an excess of counts from a given chromosome and whether that indicates that the sample may have come from an affected pregnancy.

2. Can I have additional tests performed on the specimen I send for Prenatal Screening Program through PerkinElmer?

- a. No

3. How do patients consent to additional tests?

- a. Not applicable

4. Are you CLIA-certified? Yes

- a. Sun Clinical Laboratories – CLIA# 05D0563772
- b. Allied Laboratories Inc. – CLIA# 05D0605512

Are you certified by California Laboratory Field Services (LFS)? Yes

- a. Sun Clinical Laboratories – CLF# 3676
- b. Allied Laboratories, Inc. – CLF# 21

5. Where is the location of your lab(s) where my patients' specimens will be processed in California?

The performing labs for PerkinElmer are located at:

Sun Clinical Laboratories,
9349 Telstar Ave Ste A & B,
El Monte, CA 91731

Allied Laboratories, Inc.,
453 Ravendale Dr Ste B,
Mountain View, CA 94043