

Federal Register Notice
Request For Information
Oral Fluid

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Purpose

- Solicit written comments and statements from the general public and industry stakeholders regarding a variety of issues related to oral fluid specimen drug testing, including analytes, cutoffs, specimen validity, collection, collection devices, and testing.

Analytes/Cutoffs:

- *What analytes* should be measured in oral fluid for the initial and confirmatory tests? What initial and confirmation cutoffs should be used for the oral fluid drug tests? Should the oral fluid drug testing panel be expanded to include schedule II prescription medications?

Specimen Validity:

- Are bio-markers needed to validate the oral fluid specimen? Are there appropriate biomarkers or tests for the oral fluid specimen that would reveal adulteration, substitution, and/or dilution?

Collection:

- How should an oral fluid specimen be collected? For an oral fluid split specimen collection, how should the collection of the two specimens be performed? As a donor, would you prefer to provide an oral fluid or a urine specimen?

Collection Devices:

- What should be the technical requirements for an oral fluid specimen collection device?

Testing:

- What technologies are available to perform initial and confirmatory testing on oral fluid specimens?

Comment Process

- 60 Day Comment Period
 - June 10, 2011 – August 9, 2011
- Comment Methods
 - Regular mail / express mail
 - Electronically / fax
 - <http://www.regulations.gov/#!documentDetail;D=SAMHSA-2011-0001-0001>

Comments Received

- Nationwide Medical Review
- Immunalysis Corporation

Questions?