

MRO ALERT ADVISORY

Use of Old CCF On and After December 1, 2011 May Result in Delays at Laboratory and Specimens Being Rejected for Testing.

Significant Problems Anticipated

Federally Certified Laboratories have been directed by HHS to “Reject for Testing” specimens collected with the “old Custody and Control Form” received on and after December 1, 2011. The laboratory that receives a specimen on the old form is required to seek and receive a “memo from the collector” explaining the use of the old form. This memo must be received by the lab in order to report results to the MRO, and if this corrective memo is not received in 5 days the specimen is to be “Rejected for Testing”. See the NLCP notice to HHS-Certified Laboratories below:

When the laboratory reports that a specimen is “rejected for testing” to the MRO, § 40.199 (a) requires the MRO to report the specimen as *cancelled*.

§ 40.199 What problems always cause a drug test to be cancelled?

(a) As the MRO, when the laboratory discovers a “fatal flaw” during its processing of incoming specimens (see §40.83), the laboratory will report to you that the specimen has been “Rejected for Testing” (with the reason stated). You must always cancel such a test. ...

The following notice was sent to the Certified Laboratories by the NLCP (National Laboratory Certification Program)

Attention: HHS-Certified and Applicant Laboratories and National Laboratory Certification Program (NLCP) Inspectors

This is a reminder that the Department of Health and Human Services (HHS) and the Department of Transportation extended the use of the 2000 Federal Custody and Control Form (CCF) *through November 30, 2011*.

Beginning December 1, 2011, laboratories must use the following procedures for federally regulated specimens received with the expired Federal CCF: the laboratory processes the specimen using its standard operating procedures for regulated specimens and contacts the collector for a memorandum explaining the use of the incorrect form. The laboratory retains the specimen for at least 5 business days from the date that action is initiated to correct the CCF issue, and reports the specimen results upon receipt of the collector memorandum. If the laboratory cannot obtain a memorandum from the collector, the laboratory reports a rejected for testing result and indicates the reason for rejecting the specimen on the report to the Medical Review Officer (MRO).

Laboratories experiencing problems such as frequent delayed specimen reports or collection site non-compliance with required procedures should notify the NLCP or DOT.

MROALERT Guidance

Guidance on MRO Reporting Cancelled Results to DER

It is advisable for the MRO who has received a “Rejected for Testing” report due to use of the old form to explain the reasons to the Designated Employer Representative beyond simply “rejected for

testing-fatal flaw”. The MRO should note here what the fatal flaw is. It is advisable to note that it was because of the use of an outdated DOT CCF — and the inability of the laboratory to get a memo from the collector.

Guidance on Oversight of Collection Site

Given the above advice, it is important for any MRO who has collection sites in his or her office as part of the MRO’s practice to get the word out immediately to stop using the old CCF form (at least have a control in place to prevent using it after November 30, 2011).

Guidance to Collection Sites and Collectors — A Pre-Emptive memo?

First - Make sure that a supply of the new CCF forms is in place. You do not want to be blamed for delaying results, fatal flaws and costing employers time and money. If you cannot get new CCF forms from the laboratory, let the MRO and employer know now.

If all else fails come December 1st and, for whatever reason, a DOT urine is needed and all you have from the designated laboratory is the old CCF there is the possibility of the collector preparing what, for a lack of a better term, can be called a “pre-emptive” memo. This idea has not been vetted with HHS or DOT.

A “pre-emptive memo” would be substantively identical to the corrective memo sent to the lab after it has requested one. Sending “pre-emptive” memo with the specimen attached to the “old” CCF” would potentially save considerable time and avoid the potential for a “rejected for testing” scenario.

This “pre-emptive memo” should meet the requirements of the regulation. The worst that can happen is the lab would ask for a new memo. There is a danger of using “pre-emptive” rules as a substitute for routinely using the new CCF form because it could appear that this is simply intentional non-compliance as opposed to proactive and cooperative full compliance.

Additional Comment

Laboratories are still receiving a significant number of “old” CCF forms. The hope is that this is simply an effort to use up all the old forms. The history of changing CCF forms in this program has, however, not been good. Changing CCF forms has always been an expensive process.

This transition may be as painful, but in light of the above required procedures in place at the labs, it probably will be shorter. Employers, program administrators, and the laboratories are not going to tolerate a high number of rejected specimens and collectors are not going to want to write too many memos or have too many complaints.

DOT has done what it can short of a full page add in USA Today and advertisements during football games to remind everyone that the old CCF is in its last days of use in the DOT and Coast Guard drug testing programs. Most of the laboratories have advised collection sites.

Unfortunately, in addition to costs to the service providers in seeking memos and otherwise delayed reporting, there may be significant adverse consequences resulting from “rejected for testing” specimens. The most common problem with canceled tests is delaying hiring decisions and requiring new urine tests. It is also foreseeable that these procedures could result in the cancelation of important reasonable suspicion and post accident test results.