

2019 WL 7546328 (N.D.Ind.) (Expert Report and Affidavit)
United States District Court, N.D. Indiana.

United States of America et al.,

v.

WAGONER et al.

No. 2:17-CV-00478.

October 31, 2019.

Expert Medical Review of Timothy Earl King, M.D.

Name of Expert: [Timothy Earl King, M.D.](#)

Area of Expertise: Medical & Surgical >> Pain (Chronic) Management

Representing: Plaintiff

Jurisdiction: N.D.Ind.

Purpose

- A professional opinion is rendered as to proper CPT 2011 coding for the *One Step Multi-Drug Urine Test Panel* (multiplex screening kit) as utilized and billed by Dr Wagoner and the Wagoner Medical Clinic, LLC.

Materials Reviewed

- Amended Complaint - USA & State of Indiana v. Don Wagoner & WMC
- CPT Coding: UDS 2011
- CPT Assistant: Fall 1993
- CPT Assistant: Dec 2010
- Provider Bulletin: March 2009
- Package Insert: *One Step Multi-Drug Urine Test Panel*
- produced pursuant to subpoena from Wagoner Medical Center (WMC) records during execution of search warrant on February 7, 2013
- Urine Drug Test Package
- photograph taken during execution of search warrant of WMC on Feb 7, 2013
- Urine Drug Test Card
- photograph taken during execution of search warrant of WMC on Feb 7, 2013

Opinion

Code 80104 is the proper code for multiplex screening kit testing as represented by the *One Step Multi-Drug Urine Test Panel*. This drug test, as used by the Wagoner Medical Center (WMC), is described as a “competitive immunoassay that is used to test for the presence of drugs of abuse in urine”, (*Package Insert produced from WMC records on February 7, 2013*). This type of dip stick testing is different from the chromatographic method as exemplified by thin layer chromatography (TLC) or gas chromatography (GC). Competitive immunoassay testing, such as represented by the *One Step Multi-Drug Urine Test Panel*, is based on dipstick technology (absorption by capillary action followed by antigen/antibody reaction), not on chromatographic technology that depends on “separation of substances by differential absorption into a moving 2-phase system”, (*CPTAssistant Fall 1993*).

The *One Step Multi-Drug Urine Test Panel* is an office-based point-of-care test “for the qualitative detection of drugs of abuse and their metabolites in human urine”, (*Package Insert*). The entire test takes 5 minutes and requires no specialized personnel or specialized laboratory equipment. Results are presented visually in the form of a horizontal band. If the band is visible, then the test is negative - i.e. the drug is absent. If the band is not visible, then the test is positive - i.e. the drug is present. Unlike the chromatographic method, dipstick methodology has no need for component separation, complex detection, or specialized equipment.

“Rapid one step drug testing”, as described in the *One Step Multi-Drug Urine Test Panel* package insert, (properly coded 80104), is distinct and separate from older and more complex drug testing methodology that depends on chromatographic separation, differential absorption, and multiphase systems, (properly coded 80100 or 80101). The wide availability and low complexity associated with newer dipstick technology has supplanted the use of older and more traditional laboratory based chromatographic methods for qualitative drug testing. The corresponding change in CPT coding is plainly stated in the *CPTAssistant: Dec 2010*:

- “Qualitative screen analysis using a multiplexed screening kit for multiple drugs or drug classes is reported with the new CPT code 80104”.

Dr Wagoner inappropriately uses CPT code 80101 to bill for drug testing performed with the *One Step Multi-Drug Urine Test Panel*. The multiplexed screening kit, as used by the Wagoner Medical Clinic, does not use chromatographic methodology to determine the presence or absence of drugs. It uses a competitive binding immunoassay methodology analogous to that used for dip stick pregnancy testing. Dip stick methodology employs a mixture of specific antigens and antibodies to selectively detect specific drugs but does not require separation of components, sophisticated laboratory equipment, or complexity of process. Dip stick testing requires placement into a urine sample and then noting presence or absence of a horizontal band. The test is a “rapid one step test for the qualitative detection of drugs of abuse”, (*Package Insert*). The proper code for dipstick, non-chromatographic drug testing is 80104 - clearly delineated in the *CPT Manual 2011* and reaffirmed in the *CPTAssistant: Dec 2010*.

The chromatography (non-dip stick) method involves complex sample preparation (into a liquid or gas phase), introduction of a sample into a stationary phase (liquid or solid medium), movement of a sample thru a stationary phase (using pressurized gas or liquid), and ultimate identification of separated components (using fluorescence, conductivity, mass spectroscopy, or a photo-chemical reaction). This is a complex process involving sophisticated devices, calibrated equipment, and substance reference lists. A pathologist or toxicologist with specialized training is required for proper interpretation of the results.

To better understand process complexity and equipment requirements, an example of the chromatographic method is represented below:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

The *One Step Multi-Drug Urine Test Panel* is a non-chromatographic method that does not depend on component separation, sophisticated analyte development, or a pathologist/toxicologist to interpret the results. It is a simple technology widely used for testing many medical conditions including pregnancy, Lyme disease, strep throat, and autoimmune disorders. The *One Step Multi-Drug Urine Test Panel* is not a chromatographic method and does not use chromatography as defined by *CPTAssistant: Fall 1993*:

- Chromatography: absorption analysis; the separation of chemical substances by differential absorption into a moving, 2-phase system. In gas-liquid chromatography, gaseous substances are separated by movement through a liquid phase.”

The simplified dip stick methodology associated with use of the *One Step Multi-Drug Urine Test Panel* is illustrated below. Photos of an unopened pouch (#1), Urine Test Panel card (#2), and information graphic (#3) are represented. Photo nos. 1 & 2 were taken at WMC during execution of a search warrant on February 7, 2013. Photo no. 3 is an image within a multiplexed screening kit package insert produced from WMC's records pursuant to subpoena on February 7, 2013. The pouch is opened, the test card is placed into the urine cup, and results are read 5 minutes later. No further analysis is required.

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

A physician with ordinary competence would understand the CPT Manual's instructions to use code 80104 for qualitative analysis when using a multiplexed screening kit (*One Step Multi-Drug Urine Test Panel*), such as employed by the Wagoner Medical Center. This dip stick methodology does not depend on component separation, nor does it require sophisticated instrumentation or specialized personnel.

CPT coding reflects the complexity of a process. In the past, when simple dipstick technology was not readily available and qualitative chromatographic testing had to be carried out in a laboratory environment, then codes 80100 and 80101 were appropriate. However, this has not been the case since 2011 when dipstick technology (multiplexed screening kits) became widely available. *CPT2011* clearly states:

- “For qualitative analysis by multiplexed screening kit for multiple drugs or drug classes, use 80104.”

CPTAssistant: Dec 2010 further emphasizes proper use of code 80104 when using a multiplex screening kit, (i.e. The *One Step Multi-Drug Urine Test Panel*):

- “More recently point of care and other testing can be used to identify multiple drug classes in a single test procedure. However, these assays do not utilize a chromatographic method, making code 80100 inappropriate to use. They may rely on immunoassays, for example. Kits are available for 12 or more analytes. These test kits are often called “multiplexed” because of the ability to qualitatively assay multiple drugs simultaneously. It is effectively running multiple tests at once, in a single procedure, due to the test kit design.”

- “In 2010 a HCPCS code G0430 was created to describe a non chromatographic method wherein multiple drug classes were screened in a single procedure. New code 80104 represents this same procedure, more accurately reflecting the resources used in a multiplex kit as compared to multiple runs using a single class technology.”

Drug testing using the *One Step Multi-Drug Urine Test Panel* must be submitted as code 80104, not as multiple submissions of 80101. Multiplexed screening kits utilize “other than chromatographic methods” (*CPT2011*), do not depend on component separation, do not require a “combination of stationary and mobile phases” (*CPT2011*), do not require sophisticated instrumentation, and do not require specialized personnel (pathologist or toxicologist). Dipstick technology offers simplistic, low complexity, point-of-care use, and thus serves as “a rapid one-step test” (*Package Insert*). Code 80104 is easily understood and generally recognized to be the proper code when using the *One Step Multi-Drug Urine Test Panel*.

Modifier -91 represents testing performed on the same day for purposes of obtaining critical sequential results, i.e. blood sugar, electrolytes, or other values that would be expected to change in a critical manner over a short timeframe. The use of a code -91 modifier is never applicable when a multiplex screening device is used for urine drug testing. It takes days or weeks to observe significant changes in urine drug levels. Dipstick drug testing is used to monitor patient compliance and is not intended for same day sequential testing.

The -91 modifier is not used “when a normal, one-time, reportable result is all that is required”; (Provider Bulletin 2009). Modifier -91 is never applicable in the context of drug toxicology because there is no medical need for short term sequential testing for drugs of abuse. Code 80104 is recognized to be the proper code when utilizing a multiplex screening kit.

Immunoassay testing utilizes the unique relationship of antibody and antigen as the foundational methodology for dipstick drug testing. The chromatographic method utilizes separation of components by selective absorption, mobile and stationary phase migration, fluorescence and photo-chemical analysis for detection, and specialized personnel for interpretation of results. Dr Wagoner and the Wagoner Medical Clinic incorrectly apply code 80101 and -91 modifiers to multiplexed drug testing. A physician specializing in the treatment of pain or a family practice physician with ordinary competence would understand that 80104 is the proper code for qualitative multiplexed drug testing, i.e. The *One Step Multi-Drug Urine Test Panel*.

Application of UDS Testing by WMC

Thirty-one medical records from the Wagoner Medical Clinic were previously examined as part of an expert review to determine if controlled substances were prescribed for a legitimate medical purpose and within the usual course of medical practice. Of the 31 charts, 29 were reviewed specifically for evidence of inconsistent urine drug screens. Multiple urine drug screens (UDS's) showed major inconsistencies:

- Presence of illegal substances or alcohol (THC, methamphetamine, EtOH)
- Presence of non-prescribed drugs
- Absence of prescribed drugs.

In total, a review of 29 patient files revealed 235 point-of-care (dipstick) inconsistencies. In no instance was there evidence of treatment plan modification or cessation of opiates as a result of drug inconsistencies. Patients were not held accountable for aberrant behavior or noncompliant drug use. Controlled substances were not stopped despite treatment inefficacy. Controlled substance prescriptions were issued, refilled, and chronically maintained despite failure of pain management, evidence of ongoing addiction, and illegal drug dependency. Urine drug screens, despite showing objective evidence of ongoing abuse, diversion, and addiction, were not used to objectively or meaningfully monitor or enforce the use of controlled substances.

The Wagoner Medical Clinic employed urine drug testing on a frequent basis but never applied the results to patient care. Drug test results were routinely ignored and therefore served no legitimate medical purpose.