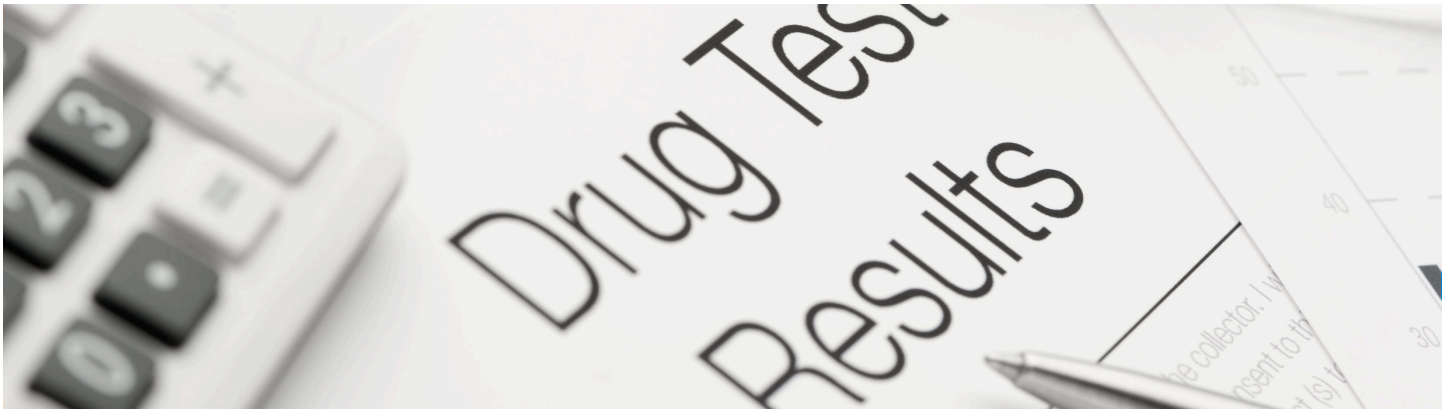

Negative Dilute Drug Screening Results

Understanding The Outcome And Its Implications

Positive drug screen results can pose problematic scenarios for employers and can potentially complicate or lengthen the hiring process. Any returned result identified as non-negative (including negative dilute) is likely to cause concern and raise questions as to what the result implies.

The "negative dilute" scenario will be explored and discussed in this ComplianceAlert, including what implications that type of result may carry.

Specimen Testing

Understanding how laboratories test urine specimens is critical in interpreting and evaluating an associated test result. The lab's initial set of tests are called **validity tests**. These tests are designed to discern whether the urine specimen submitted meets the criteria for being *human* urine. These tests also identify the presence of any synthetic urine, adulterants or substances used to modify the sample. Criteria used in validity testing includes[1]:

- **Creatinine**
  This is a measurement of a person's muscle mass. Normal values are above 20mg/dl.
- **Specific gravity**
  This indicates the concentration of particles in urine. Normal values typically range between 1.003 and 1.03. Specific gravity is tested if creatinine levels are less than 20 mg/dl.
- **pH levels**
  This is a measurement of acid/alkali in the urine. Normal values typically range between 4.5 and 9.0.
- **Oxidizing adulterants (one or more)**

If all test results for these criteria are within the acceptable range, the specimen progresses to the next testing stage - the **screening test** or **immunoassay test**. If the specimen yields negative results in this phase of screening, no further testing is required. However, if the immunoassay test is positive, a **confirmation test** is conducted for the substance identified on the immunoassay test. The confirmation test is usually performed via Gas Chromatography/Mass Spectrometry (GC/MS).

[1] The Medical Review Officer's Manual, 5th edition by Dr Robert B. Swotinsky

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Dilute Result Criteria

In performing validity tests, there are instances in which the specimen is determined to be dilute. A dilute specimen is defined as exhibiting creatinine and specific gravity values *lower than expected but still within physiologic range*. The lab criteria required to label a sample as dilute are[2]:

- **Creatinine:**
  Below 20 mg/dl but above 2mg/dl.
- **Specific gravity:**
  Below 1.003 but above 1.0010.

The specimen is considered dilute when both measurements fall within the above ranges. If either result is outside of this range, then the outcome may be designated as "Invalid", "Adulterated" or "Substituted".

If possible, a lab will try to perform screening tests on all samples, so a specimen can still be tested via screening or immunoassay test even if the initial validity test measurement results are not within the acceptable range. In this phase, the dilute specimen is tested using a screening test for drugs. If this screening test result is negative, the result is reported as **negative dilute** and no further testing is required. If this screening test result is positive for a substance, a confirmation test is performed for that specific substance. As such, **positive dilute** results are possible.

Reasons For A Dilute Specimen

According to literature, about five percent of specimens meet dilute criteria[3]. Occurrence of dilute specimens can be attributed to multiple reasons, a few of which are highlighted below.

- Hydrating before the drug test to mitigate the possibility of not being able to produce a sample upon arriving at the lab
- Advice of a physician to drink plenty of water as part of a healthy routine (i.e. weight loss, prevent kidney stones, etc.).
- Certain medical conditions and medications (i.e. types of kidney disease, use of diuretics, etc.).
- Intentional over-hydration in an effort to avoid drug detection

Employers should consider all these scenarios, as many times the reason for a dilute specimen could be less nefarious than is initially thought.

Protocol For Employers

Federal regulations do not authorize any disciplinary action for dilute results other than retesting the donor in the event of a negative dilute. Depending on a company's policy, employers may retest the donor if it is dilute . However, if the specimen is extremely dilute (creatinine of 2-5mg/dl) the employer *must* retest under direct observation[4]. If the second specimen test result is also returned as dilute, then that is considered a final result and no further tests are performed. The second negative dilute is accepted as a negative test result.

In settings outside of federal regulations, handling of negative dilute results should be consistent per an organization's Workplace Drug testing policy. Maintaining a clear policy of whether to retest such donors or accept the result as negative helps avoid any ambiguity and inadvertent discriminatory actions.

Employers can facilitate the hiring process with more confidence by keeping in mind this broad perspective about "dilute" specimens and crafting a clear and consistent policy to address these situations.

[2] https://www.samhsa.gov/sites/default/files/workplace/mro_guidance_manual_508_final_march_2018.pdf: Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs

[3] https://www.federalregister.gov/documents/2017/01/23/2017-00979/mandatory-guidelines-for-federal-workplace-drug-testing-programs#h-29: Mandatory Guidelines for Federal Workplace Drug Testing Programs

[4] *Id.*