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Assay Effective in Identifying Synthetic Urine Products - Potential Solution for Workplace and Clinical Drug Testing

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Abstract

Introduction: Using synthetic urine products to "beat" urine drug tests has become a business, with a wide range of commercial products available. The prevalence of synthetic urine use differs by testing purpose and population but has been reported to be 2-3%, similar to total drug positivity in some programs. Synthetic urine products are designed to register as authentic urine in common Specimen Validity Tests (SVT) including creatinine, pH, oxidants, and uric acid. The products can be identified by measuring panels of endogenous analytes by LC-MS/MS. However, LC-MS/MS methods are expensive as an initial test in workplace or clinical drug testing. Recently, Validity Diagnostics (Orlando, FL) introduced the True Urine Long and Short Duration Immunoassay SVTs, that identify authentic urine specimens by the presence of different urinary tract proteins. The assay can be operated using an automated analyzer and could potentially be used as an initial test to identify synthetic urine.

Objectives: To determine the sensitivity and specificity of the True Urine Long and Short Duration Assays by conducting an independent proof-of-concept study. A laboratory routinely using the assays was contracted for the analysis, but neither the laboratory or the manufacturer contributed to the study design, data evaluation or dissemination.

Methods: Fifteen synthetic urine products (purchased online in December 2024), 80 fresh deidentified urine specimens, and 16 older frozen specimens (four with pH 8.6-8.7 and four with pH 4.7-4.8) were included in the test (n=111). All samples were analyzed with the True Urine Long and Short Duration assays with the laboratory routine cutoffs. The synthetic urine specimens were verified by a qualitative LC-QTOF-MS assay measuring creatinine, theobromine, paraxanthine, and three unidentified chromatographic features previously found to be present in authentic urine (*m/z* 185, 229 and 265).

Results: While all synthetic urine samples contained creatinine, none contained theobromine, paraxanthine, or any of the chromatographic features, confirming them as synthetic urine products. The Long Duration assay correctly identified 14/15 synthetic urine

products (93% sensitivity), as well as all fresh urine specimens (80/80) and 15/16 of the frozen ones (95/96, 99% specificity). The Short Duration assay correctly identified 8/15 synthetic urine products (53% sensitivity), as well as 78/79 fresh urine specimens and all frozen urine specimens (94/95, 99% specificity). The synthetic urine product incorrectly identified as authentic urine by the Long Duration Assay was also incorrectly identified as authentic urine by the Short Duration Assay. No result was obtained for one of the fresh urine specimens using the Short Duration Assay (clot detected flag).

Discussion: The True Urine assays, and especially the Long Duration assay, correctly identified synthetic urine products. The sensitivity was high enough to act as a deterrent to synthetic urine product use and high selectivity will minimize subsequent confirmation testing. When uric acid was introduced as a potential synthetic urine initial test, manufacturers quickly pivoted to include uric acid in the products. However, urinary tract proteins are expected to be difficult and expensive to source and formulate making it more difficult for the manufacturers to overcome. In conclusion, the True Urine Long Duration Assay successfully identified synthetic urine products with high sensitivity and specificity, showing potential to serve as a synthetic urine initial test in combination with a mass spectrometry based confirmatory testing in clinical and workplace drug testing.

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Disclosure

No, I, nor any member of my immediate family, has a financial interest to disclose.