

VALIDATION SUMMARY	
Procedure Name	Benzodiazepines from Blood and Urine by LC/MS (MRM) TOX426-7 (Update for Process Control: oxazepam glucuronide)
Validation Summary	<p>Four batches consisting of three lot of blank urines and one lot of surine were analyzed [Extraction scheme (#14): NC Urine a-c, PCU Low a-c (oxaz gluc), PCU High a-c (oxaz gluc), NC Surine, PCS Low (oxaz gluc), PCS High (oxaz gluc), PCS Low (reg pc soln) & PCS High (reg pc soln)]. Hydrolysis controls were analyzed at free oxazepam concentrations of ~ 1 ng/mL and ~ 10 ng/mL. Oxazepam glucuronide controls were compared to oxazepam controls after hydrolysis.</p> <p>Recovery of cleaved (unlabeled) oxazepam in the positive controls was within $\pm 50\%$ of the expected response (ranging from 64 to 110%), meeting the acceptance criteria for this process control.</p> <p>Lipomed oxazepam-glucuronide.tfa solution (0.1 mg/mL free base/1 mL acetonitrile) was utilized to conduct the first hydrolysis batch. Per the manufacturer's certificate of analysis, this reference material is not suitable for hydrolysis or immunoassay (> 90 % R-isomer); no hydrolysis was demonstrated with this batch.</p> <p>Mass spectra ion ratios were evaluated for the 1 ng/mL hydrolysis controls against the regular oxazepam control and showed to pass criteria.</p>

APPROVALS			
Technical Approval	Redacted	Date	4/18/2023
Unit Chief Approval		Date	4/18/23

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