



Evaluation of Oral Fluid Drug Collection POC Devices by CRL

Introduction: This white paper summarizes the findings of an independent evaluation conducted by CRL on a series of oral fluid point of care (POC) drug collection devices. The primary objective was to assess the performance of the drug test strips contained within these devices against the manufacturer stated cutoff levels, a critical factor for accurate and reliable drug screening in various applications.

Method: The evaluation protocol involved the preparation of control solutions at three distinct concentrations relative to each drug's specified cutoff level: 0% (negative control), 50% (intermediate control), and 150% (positive control). Each oral fluid POC device underwent testing in accordance with its manufacturer's package insert instructions. Following the application of the control solutions, all test strips were incubated, photographed and interpreted based on the guidance provided by the respective manufacturers. A device was deemed to have failed the evaluation if any of its individual drug test strips failed to produce a positive result at the 150% cutoff concentration or a negative result at the 0% concentration. This ensured that even a single non-compliant strip would lead to an overall "Fail" status for the device, emphasizing the importance of comprehensive accuracy.

Results: CRL's evaluation encompassed a diverse range of oral fluid devices from an array of suppliers, including OraSure, Abbott, Premier Bio, W.H.P.M., Wondfo, Healgen, mLife, Novir, nform, and Advin. These devices covered various drug panels, including 4-drug, 6-drug, 10-drug, and 11-drug configurations, as well as a single drug test for THC. The results indicated a varied performance landscape across the devices and drug panels tested, including different lots of the same device. While several devices demonstrated successful performance, achieving a "Pass" status by correctly identifying both positive (150% cutoff) and negative (0% cutoff) controls across all included drug strips, a significant number of devices, or specific drug strips within devices, failed to meet performance standards. These failures were noted in Table 1 across a wide range of commonly screened drugs (noted in red), including but not limited to Amphetamines (AMP), Benzodiazepines (BZO), Cocaine (COC), Methamphetamines (MET), Opiates (OPI), Tetrahydrocannabinol (THC), Phencyclidine (PCP), Methadone (MTD), Oxycodone (OXY), Barbiturates (BAR), Buprenorphine (BUP), and Methylenedioxymethamphetamine (MDMA). This evaluation identified numerous instances where individual drug test strips within a device did not consistently perform at their specified cutoff levels, leading to an overall "Fail" status for the entire device. A few POC devices, including the 1Step Oral 11 Panel, Abbott, nform, and Novir devices, did meet their specified drug cutoff levels for all strips, and their results are highlighted in green in Table 1. Passing POC devices containing THC strips included the 1Step Oral 11 Panel, nform-7, and Novir InstaCLEAR - 8 panel devices.



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It is worth noting that many of the drug cutoff levels for the test strips in these OF POC devices are considerably higher than the average levels measured in donor samples in the laboratory. For instance, in analyzing CRL's 2024 data, 45% of THC positive oral fluid donor samples had levels between 0.2 to 4 ng/mL, and 34% had THC levels between 4.1 to 14.9 ng/mL. Any devices with THC strip cutoffs of 15 ng/mL or greater would miss 79% of CRL's positive OF THC samples and yield a false negative result. See Figure 1 for a comparison of CRL's OF THC levels and POC cutoff levels.

Conclusion: This CRL evaluation underscores the importance of independent testing for oral fluid drug POC collection devices. The findings reveal inconsistencies in the ability of some devices to reliably detect target drugs at critical concentrations, emphasizing the need for manufacturers to ensure their products consistently perform according to specified cutoff levels. For laboratories, employers, and other end-users, these results highlight the necessity of independent validation to select POC devices that deliver consistently accurate and dependable drug screening outcomes, thereby supporting effective and reliable testing programs. Continued vigilance in device selection and regular performance validation for new device lots are crucial for maintaining the integrity and efficacy of oral fluid POC drug testing.

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Table 1: Oral Fluid POC Device Evaluation

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Product Description	Supplier	Item Lot #	Result	Drugs / Cutoffs
1Step Oral 11 Panel	Advin	Multiple	Pass	MET50 COC20 AMP50 OPI40 BAR50 BZO10 MDMA50 MTD30 OXY20 PCP10 THC40
ORAL FLUID - 10 DRUG	ORASURE TECHNOLOGIES, INC.	B2408084	Fail	AMP50 BAR50 BZO10 COC20 COT50 MET50 MTD30 OPI40 PCP10 THC40
ORAL FLUID - 4 PANEL	Abbott	D2501068	Pass	AMP50 COC20 MET50 OPI40
ORAL FLUID - 4 PANEL	Abbott	D2049017	Pass	AMP50 COC20 MET50 OPI40
ORAL FLUID - 10 DRUG	ORASURE TECHNOLOGIES, INC.	T2400020	Fail	AMP50 BAR50 BZO10 COC20 COT50 MET50 MTD30 OPI40 PCP10 THC40
ORAL FLUID - 6 DRUG (OT-80602)	Premier Bio	B2407005	Fail	AMP50 COC20 MET50 OPI40 PCP10 THC40

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Product Description	Supplier	Item Lot #	Result	Drugs / Cutoffs
ORAL FLUID - 10 DRUG (OT-81005)	Premier Bio	T2300024	Fail	AMP50 BAR50 BZO10 COC20 COT50 THC40 MTD30 MET50 OPI40 PCP10
ORAL FLUID - 10 DRUG	W.H.P.M. Inc	PD-07031	Fail	AMP50 BAR50 BZO10 COC20 MET50 MTD30 OPI40 OXY20 PCP10 THC50
ORAL FLUID - 10 DRUG	W.H.P.M. Inc	PC-12006	Fail	AMP50 BAR50 BZO10 COC20 MET50 MTD30 OPI40 OXY20 PCP10 THC50
ORAL FLUID - 10 DRUG	W.H.P.M. Inc	PC-08025	Fail	AMP50 BAR50 BZO10 COC20 MET50 MTD30 OPI40 OXY20 PCP10 THC50

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Product Description	Supplier	Item Lot #	Result	Drugs / Cutoffs
ORAL FLUID - 10 DRUG	W.H.P.M. Inc	PC-11007	Fail	AMP50 BAR50 BZO10 COC20 MET50 MTD30 OPI40 OXY20 PCP10 THC50
ORAL FLUID - 4 PANEL	Abbott	D2306362	Pass	AMP50 COC20 MET50 OPI40
ORAL FLUID - 4 PANEL	Abbott	D2502012	Pass	AMP50 COC20 MET50 OPI40
ORAL FLUID - 4 PANEL	Abbott	D2412268	Pass	AMP50 COC20 MET50 OPI40
nform-THC	nform	N/A	Pass	THC4
nform-7	nform	N/A	Pass	AMP50 COC15 MET50 OPI30 6AM4 OXY30 PCP10
mLife Verify	mLife	N/A	Fail	AMP50 COC20 MET40 OPI40 PCP10
Novir InstaCLEAR - 8 panel	Novir	DOA2504047	Pass	BZO20 AMP50 OPI40 COC20 MET50 BAR50 OXY20 THC15

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Product Description	Supplier	Item Lot #	Result	Drugs / Cutoffs
SalivaConfirm OF Drug Test Cube / Orient Gene Biotech	Healgen	Multiple	Fail	AMP50 BAR300 BUP10 BZO50 COC20 OPI40 MTD75 MET50 MDMA50 OXY50 THC40 FEN5 ALC0.02
Safelife T-Square Multi-Drug Oral Fluid Device	Wondfo	W610406003	Fail	AMP50 BAR20 COC20 OPI40 OXY20 PCP10 MDMA50 MET50 MTD30 THC40



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Figure 1:

