



ACCOUNT INFORMATION		PATIENT INFORMATION																																																																																																																																																																																																																																	
<p>The ordering physician must sign his/her name and indicate the date the test is ordered. The signature constitutes as a certification, that with respect to tests reimbursed by Medicare, Medicaid, or other third party payers that the testing is medically necessary and the results will be used in the management of the patient.</p> <p>X _____ Physician Signature Date</p>		<p>Last Name First Name</p> <p>D.O.B (MM/DD/YY) Sex <input type="checkbox"/> M <input type="checkbox"/> F</p> <p>Phone (Day) (Evening)</p> <p>Insured's Address Apt.</p> <p>City State Zip</p> <p>I voluntarily consent to the collection and testing of my specimen. I certify that the specimen on this form is my own, and that the specimen is fresh and free from adulteration. I certify that the information provided on this form and on the label on the specimen sample is accurate. I authorize Clarity Labs to release the results of this testing to the treating physician or facility. I have read and understood the ABN printed on the backside of this form.</p> <p>X _____ Patient Signature Date</p>																																																																																																																																																																																																																																	
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<p>VALIDATED RISK ASSESSMENT <input type="checkbox"/> LOW <input type="checkbox"/> MODERATE <input type="checkbox"/> HIGH</p> <p>REASON FOR TEST</p> <table border="0" style="width:100%;"> <tr> <td><input type="checkbox"/> New patient requires COT</td> <td><input type="checkbox"/> Sudden change in patient's medical condition</td> </tr> <tr> <td><input type="checkbox"/> Patient side effect profile changes</td> <td><input type="checkbox"/> Substance Use Disorder (SUD); Patient in treatment program</td> </tr> <tr> <td><input type="checkbox"/> Patient tested positive for undisclosed substance</td> <td><input type="checkbox"/> Unreliable patient history</td> </tr> <tr> <td><input type="checkbox"/> Previous test revealed non-compliance to prescription</td> <td><input type="checkbox"/> COT monitoring test</td> </tr> <tr> <td><input type="checkbox"/> Patient response to prescribed medication suddenly changes</td> <td><input type="checkbox"/> Change in medication</td> </tr> <tr> <td><input type="checkbox"/> Assess for possible drug-drug interactions</td> <td></td> </tr> </table> <p><small>The clinician must always document clear medical reason and necessity in progress notes.</small></p>		<input type="checkbox"/> New patient requires COT	<input type="checkbox"/> Sudden change in patient's medical condition	<input type="checkbox"/> Patient side effect profile changes	<input type="checkbox"/> Substance Use Disorder (SUD); Patient in treatment program	<input type="checkbox"/> Patient tested positive for undisclosed substance	<input type="checkbox"/> Unreliable patient history	<input type="checkbox"/> Previous test revealed non-compliance to prescription	<input type="checkbox"/> COT monitoring test	<input type="checkbox"/> Patient response to prescribed medication suddenly changes	<input type="checkbox"/> Change in medication	<input type="checkbox"/> Assess for possible drug-drug interactions		<p>Date Collected: ____/____/____ Time: ____:____ Collector: _____</p> <p>Temperature read within 4 mins and is in range of 32.5-37.7°C (90.5-100°F) <input type="checkbox"/> Yes <input type="checkbox"/> No</p>																																																																																																																																																																																																																					
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4 ORDER TESTS		RECORD POINT-OF-CARE RESULTS & ORDER TESTS																																																																																																																																																																																																																																	
<p>SPECIMEN TYPE <input type="checkbox"/> Urine (Ur) <input type="checkbox"/> Oral Fluid (OF)</p> <p>PRESUMPTIVE IMMUNOASSAY TESTING</p> <p>UDS <input type="checkbox"/> OFDS <input type="checkbox"/> Presumptive immunoassay drug screen only (Ur)* (OF)**</p> <p>UDSC <input type="checkbox"/> OFDSC <input type="checkbox"/> Presumptive drug screen and confirm all positives (Ur)* (OF)**</p> <p>SVT <input type="checkbox"/> Perform Specimen Validity (Ur) (Creatinine, pH, Specific Gravity, Oxidants)</p> <p><small>* (AMP, BARB, Benzo, BUP, THC, COC, Ecstasy, ETG, ETOH, 6AM, MTD, EDDP, OPI, OXY, PCP, Fant, Spica 1 (WHD18), Creatinine, pH, Specific Gravity, Oxidants) ** (AMP, Methamp, Benzo, COC, MTD, BUP, OPI, OXY, PCP, THC)</small></p>		<p>NOTE: If Point-of-Care result is NOT marked, it will default to a Negative (-) result.</p> <p>POC billed by ordering provider: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <table border="1" style="width:100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">POC RESULTS</th> <th rowspan="2">CONF TEST</th> <th rowspan="2"></th> <th colspan="2">POC RESULTS</th> <th rowspan="2">CONF TEST</th> </tr> <tr> <th>POS (+)</th> <th>NEG (-)</th> <th>POS (+)</th> <th>NEG (-)</th> </tr> </thead> <tbody> <tr> <td>U12 MARIJUANA [THC]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U9 BARBITURATES [BAR]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U13 COCAINE [COC]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U10 BENZODIAZEPINE [BZO]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U23 OPIATES [OPI]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U20 METHADONE [MTD]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U3 AMPHETAMINES [AMP]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U6 TRICYCLIC ANTIDEPRESSANTS [TCA]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U3 METHAMPHETAMINE [MET]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U25 OXYCODONE [OXY]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U26 PHENCYCLIDINE [PCP]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U11 BUPRENORPHINE [BUP]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>U19 ECSTASY [MDMA]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td>U23 MORPHINE [MOR]</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>			POC RESULTS		CONF TEST		POC RESULTS		CONF TEST	POS (+)	NEG (-)	POS (+)	NEG (-)	U12 MARIJUANA [THC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U9 BARBITURATES [BAR]	<input type="checkbox"/>	<input type="checkbox"/>	U13 COCAINE [COC]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U10 BENZODIAZEPINE [BZO]	<input type="checkbox"/>	<input type="checkbox"/>	U23 OPIATES [OPI]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U20 METHADONE [MTD]	<input type="checkbox"/>	<input type="checkbox"/>	U3 AMPHETAMINES [AMP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U6 TRICYCLIC ANTIDEPRESSANTS [TCA]	<input type="checkbox"/>	<input type="checkbox"/>	U3 METHAMPHETAMINE [MET]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U25 OXYCODONE [OXY]	<input type="checkbox"/>	<input type="checkbox"/>	U26 PHENCYCLIDINE [PCP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U11 BUPRENORPHINE [BUP]	<input type="checkbox"/>	<input type="checkbox"/>	U19 ECSTASY [MDMA]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		U23 MORPHINE [MOR]	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																												
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Duloxetine</td> <td><input type="checkbox"/> U26</td> <td>Methamphetamine</td> <td>EDDP (Methadone Metabolite)</td> </tr> <tr> <td>Fluoxetine^M, Paroxetine</td> <td>Ur</td> <td><input type="checkbox"/> U31</td> <td>Phencyclidine (PCP)</td> <td>Ur, OF</td> <td></td> <td>Methadone</td> </tr> <tr> <td>Sertraline</td> <td>Ur</td> <td><input type="checkbox"/> U14</td> <td>CANNABINOIDS, SYNTHETIC (SPICE)</td> <td>Ur</td> <td><input type="checkbox"/> U24</td> <td>Opioids and Opiate Analogs</td> </tr> <tr> <td>TCA (Tricyclic & Other Cyclics)</td> <td rowspan="3">Ur, OF</td> <td></td> <td>5-Fluoro PB-22, AB-CHMINACA</td> <td rowspan="3">Ur</td> <td></td> <td>Dextromethorphan, Meperidine^M</td> </tr> <tr> <td>Amitriptyline, Nortriptyline</td> <td></td> <td>AB-FUBINACA, AM2201 4-OH Pentyl</td> <td></td> <td></td> <td>Naloxone, Naltrexone</td> </tr> <tr> <td>NSSRI (Not Otherwise Specified)</td> <td rowspan="3">Ur</td> <td></td> <td>JWH-018 Pentanoic acid</td> <td><input type="checkbox"/> U28</td> <td><input type="checkbox"/> U48</td> <td>Propoxyphene^M</td> </tr> <tr> <td>Bupropion, Venlafaxine^M</td> <td></td> <td>JWH-018-N-4-OH Pentyl</td> <td>Ur</td> <td><input type="checkbox"/> U31</td> <td><input type="checkbox"/> U49</td> <td>Tapentadol^M</td> </tr> <tr> <td>Vilazodone</td> <td></td> <td>JWH-073, JWH-250</td> <td>Ur</td> <td><input type="checkbox"/> U32</td> <td><input type="checkbox"/> U50</td> <td>Tramadol^M</td> </tr> <tr> <td>ANTIPSYCHOTICS</td> <td rowspan="4">Ur</td> <td><input type="checkbox"/> U30</td> <td>SYNTHETIC STIMULANTS & CATHINONES</td> <td rowspan="4">Ur</td> <td><input type="checkbox"/> U23</td> <td><input type="checkbox"/> U43</td> <td>OPIATE/OPIOIDS</td> </tr> <tr> <td>Aripiprazole^M, Clozapine</td> <td></td> <td>Alpha-PVP, Butylone (Bath Salt)</td> <td rowspan="4">Ur</td> <td></td> <td></td> <td>Opiates</td> </tr> <tr> <td>Haloperidol, Olanzapine^M</td> <td></td> <td>Ethylone (Bath Salt), MDPV (Bath Salt)</td> <td></td> <td></td> <td>Codeine, 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type="checkbox"/> U49	Tapentadol ^M	Vilazodone		JWH-073, JWH-250	Ur	<input type="checkbox"/> U32	<input type="checkbox"/> U50	Tramadol ^M	ANTIPSYCHOTICS	Ur	<input type="checkbox"/> U30	SYNTHETIC STIMULANTS & CATHINONES	Ur	<input type="checkbox"/> U23	<input type="checkbox"/> U43	OPIATE/OPIOIDS	Aripiprazole ^M , Clozapine		Alpha-PVP, Butylone (Bath Salt)	Ur			Opiates	Haloperidol, Olanzapine ^M		Ethylone (Bath Salt), MDPV (Bath Salt)			Codeine, Dihydrocodeine	Quetiapine ^M , Risperidone ^M		Mephedrone (Bath Salt), Methylone (Bath Salt)			Hydrocodone ^M , Hydromorphone	ANALGESICS	Ur	<input type="checkbox"/> U2	ALKALOIDS	Ur	<input type="checkbox"/> U25	<input type="checkbox"/> U45	Morphine	Acetaminophen		Cofine (Nicotine), Mitragynine (Kratom) ^M			Oxycodone	BARBITURATES	Ur		Lysergic acid diethylamide (LSD)	Ur	<input type="checkbox"/> U29		Oxycodone ^M , Oxymorphone	Butalbital, Phenobarbital		Psilocin (Psilocybin Metabolite)			SEDATIVE HYPNOTICS	Secobarbital	Ur		Psilocybin (Magic Mushroom)	Ur		Zaleplon, Zolpidem	BENZODIAZEPINES	Ur, OF	<input type="checkbox"/> U22	<input type="checkbox"/> U42	SKELETAL MUSCLE RELAXANTS	Ur, OF	<input type="checkbox"/> U3	<input type="checkbox"/> U31	STIMULANTS	Flunitrazepam ^M , Alprazolam ^M		Carisoprodol, Meprobamate	Ur	<input type="checkbox"/> U3	<input type="checkbox"/> U31	Amphetamine	Clonazepam ^M , Diazepam ^M		Cyclobenzaprine		<input type="checkbox"/> U21	<input type="checkbox"/> U33	Ritalin (Methylphenidate)	Oxazepam ^M , Flurazepam ^M						Other	Lorazepam ^M , Midazolam ^M						Diphenhydramine (Benadryl)	Etizolam ^M , Triazolam ^M							Temazepam							<p>Date: ____/____/____</p> <p>Received by: _____ Time: ____:____ AM PM</p>	
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SPECIMEN HANDLING REQUIREMENTS:

Specimen Volume Minimum 30mL – Transported in specimen transport vial (packed in collection cup)

Acceptable Samples – 30mL transported in specimen transport vial (packed in collection cup) / 30mL minimum transported in specimen transport vial without any additives or preservatives

Transport – Room temperature

Specimen Stability – Room temperature for 7 days, refrigerated 14 days, frozen 14 days

Specimen Rejection – Preserved samples, sample cup without ID, leaked in transport

IMPORTANT MEDICARE INFORMATION TO THE BENEFICIARY: ADVANCED BENEFICIARY NOTICE (ABN)

Your physician may sometimes order laboratory testing that he or she believes to be necessary for your care, but which does not qualify for coverage under your Insurance Provider's and Medicare's standards. Insurance Providers and Medicare will only pay for services that it determines to be "reasonable and necessary" based upon the diagnosis information furnished to Clarity Laboratory by your physician. If, under your Insurance Provider's and Medicare's standards, your diagnosis does not support the testing ordered, your Insurance Providers and Medicare will deny coverage. In those cases where your Insurance Providers and Medicare denies coverage, the billing will be forwarded to you, and you will be responsible for the cost of the laboratory tests.

TO THE PROVIDER: Covered Indication for UDT (LCD L36037)

MEDICAL NECESSITY GUIDANCE:

DIAGNOSIS AND TREATMENT FOR SUBSTANCE ABUSE OR DEPENDENCE

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis. For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT. For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria: Patient history, physical examination, and previous laboratory findings; Stage of treatment or recovery; Suspected abused substance; Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol). The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

FREQUENCY OF UDT FOR SUD:

The testing frequency must meet medical necessity and be documented in the clinician's medical record.

TREATMENT FOR PATIENTS ON CHRONIC OPIOID THERAPY (COT).

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements: Patient history, physical examination and previous laboratory findings; Current treatment plan; Prescribed medication(s); Risk assessment plan.

COT BASELINE TESTING:

Initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, THC, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

COT MONITORING TESTING:

Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications. The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit. Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

NON-COVERED SERVICES

1. Blanket Orders
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
4. It is not reasonable and necessary for a physician to perform presumptive POCT (or IA testing) and order presumptive IA testing from a reference laboratory. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
5. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
6. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
 7. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
 8. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.