ClarityLabs
Testing for Better Health

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CLIA # 31D2140149

CR50001

ACCOUNT INFORMATION

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.

REQUIRED →

X _____

Physician Signature | Date

PATIENT INFORMATION

Last Name | First Name

D.O.B (MM/DD/YY) | Sex ☐ M ☐ F

Phone (Day) | (Evening)

Insured's Address | Apt.

City | State | Zip

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.

← REQUIRED

X _____

Patient Signature | Date

THIS SECTION IS TO COMPLETED BY A CLINICIAN

VALIDATED RISK ASSESSMENT ☐ LOW ☐ MODERATE ☐ HIGH

REASON FOR TEST

- ☐ New patient requires COT
- ☐ Patient side effect profile changes
- ☐ Patient tested positive for undisclosed substance
- ☐ Previous test revealed non-compliance to prescription
- ☐ Patient response to prescribed medication suddenly changes
- ☐ Assesss for possible drug-drug interactions
- ☐ Sudden change in patient's medical condition
- ☐ Substance Use Disorder (SUD); Patient in treatment program
- ☐ Unreliable patient history
- ☐ COT monitoring test
- ☐ Change in medication

The clinician must always document clear medical reason and necessity in progress notes.

3 INSURANCE INFORMATION ☐ Client Bill ☐ See Attached Insurance Forms

Insured's Name (if different from Patient)

Primary Insurance Name & Plan / Workers Comp. Carrier

Address (Insurance)

Policy ID # | Group/Plan/Book #

☐ Cash ☐ Check Received by: _____

4 ORDER TESTS

SPECIMEN TYPE ☐ Urine (Ur) ☐ Oral Fluid (OF)

PRESUMPTIVE IMMUNOASSAY TESTING

UDS ☐	OFDS ☐	Presumptive immunoassay drug screen only (Ur)* (OF)**
UDSC ☐	OFDSC ☐	Presumptive drug screen and confirm all positives (Ur)* (OF)**
SVT ☐		Perform Specimen Validity (Ur) (Creatinine, pH, Specific Gravity, Oxidants)

*(AMP, BARB, Benzo, BUP, THC, COC, Ecstasy, ETG, ETOH, 6AM, MTD, EDDP, OPI, OXY, PCP, Fent, Spice 1 (JWH018), Creatinine, pH, Specific Gravity, Oxidants)

**(AMP, Methamp, Benzo, COC, MTD, BUP, OPI, OXY, PCP, THC)

ICD 10 CODES

Please enter diagnosis code(s) in the box

_____ , _____ , _____ , _____

SPECIMEN INFORMATION

Date Collected: ____/____/____ Time: ____ : ____ Collector: _____

Temperature read within 4 mins and is in range of 32.5-37.7°C (90.5-100°F) ☐ Yes ☐ No

RECORD POINT-OF-CARE RESULTS & ORDER TESTS

NOTE: If Point-of-Care result is NOT marked, it will default to a Negative (-) result.

		POC RESULTS POS (+)	POC RESULTS NEG (-)	CONFIRM TEST
U12	MARIJUANA [THC]	☐	☐	☐
U13	COCAINE [COC]	☐	☐	☐
U23	OPIATES [OPI]	☐	☐	☐
U3	AMPHETAMINES [AMP]	☐	☐	☐
U3	METHAMPHETAMINE [MET]	☐	☐	☐
U26	PHENCYCLIDINE [PCP]	☐	☐	☐
U19	ECSTASY [MDMA]	☐	☐	☐
U9	BARBITURATES [BAR]	☐	☐	☐
U10	BENZODIAZEPINE [BZO]	☐	☐	☐
U20	METHADONE [MTD]	☐	☐	☐
U6	TRICYCLIC ANTIDEPRESSANTS [TCA]	☐	☐	☐
U25	OXYCODONE [OXY]	☐	☐	☐
U11	BUPRENORPHINE [BUP]	☐	☐	☐

CONFIRMATION TESTS BY DRUG CLASS OR INDIVIDUAL

Disclaimer: If a Drug class is ordered all individual tests present in that drug class will be tested.

SAMPLE TYPE Urine (UR)	SAMPLE TYPE Oral Fluid (OF)	TEST	TYPE
☐ U1		**ALCOHOL BIOMARKER**	
		EtG (Ethyl Glucuronide)	Ur
		EtS (Ethyl Sulfate)	Ur
		ANTICONVULSANTS	Ur, OF
☐ U16	☐ OF9	Gabapentin	Ur, OF
☐ U27	☐ OF18	Pregabalin	Ur, OF
		ANTIDEPRESSANTS	
☐ U5		SSRI (Serotonergic Class)	Ur
		Citalopram[M]	Ur
		Duloxetine	Ur
		Fluoxetine[M]	Ur
		Paroxetine	Ur
		Sertraline	Ur
☐ U6	☐ OF3	TCA (Tricyclic & Other Cyclics)	
		Amitriptyline	Ur, OF
		Nortriptyline	Ur, OF
☐ U7		NSSRI (Not Otherwise Specified)	
		Bupropion	Ur
		Venlafaxine[M]	Ur
		Vilazodone	Ur
☐ U8		**ANTIPSYCHOTICS**	
		Aripiprazole[M]	Ur
		Clozapine	Ur
		Haloperidol	Ur
		Olanzapine[M]	Ur
		Quetiapine[M]	Ur
		Risperidone[M]	Ur
☐ U4		**ANALGESICS**	
		Acetaminophen	Ur
☐ U9		**BARBITURATES**	
		Butalbital	Ur
		Phenobarbital	Ur
		Secobarbital	Ur
☐ U10	☐ OF4	**BENZODIAZEPINES**	
		Flunitrazepam[M], Alprazolam[M],	Ur, OF
		Clonazepam[M], Diazepam[M]	Ur, OF
		Oxazepam, Flurazepam[M]	Ur, OF
		Lorazepam, Midazolam[M]	Ur, OF
		Etizolam, Triazolam[M],	Ur
		Temazepam	Ur, OF

SAMPLE TYPE Urine (UR)	SAMPLE TYPE Oral Fluid (OF)	TEST	TYPE
		ILLICITS	
☐ U17	☐ OF10	6MAM (Heroin Metabolite)	Ur, OF
☐ U13	☐ OF7	Benzoylecgonine (Cocaine Metabolite)	Ur, OF
☐ U18		Ketamine[M]	Ur
☐ U12	☐ OF6	Marijuana[M]	Ur, OF
☐ U19	☐ OF11	MDA (Ecstasy)	
		MDA	Ur, OF
		MDEA	Ur, OF
		MDMA	Ur, OF
☐ U3	☐ OF2	Methamphetamine	Ur, OF
☐ U26	☐ OF17	Phencyclidine (PCP)	Ur, OF
☐ U14		**CANNABINOIDS, SYNTHETIC (SPICE)**	
		5-Fluoro PB-22	Ur
		AB-CHMINACA	Ur
		AB-FUBINACA	Ur
		AM2201 4-OH Pentyl	Ur
		JWH-018 Pentanoic acid	Ur
		JWH-018-N-4-OH Pentyl	Ur
		JWH-073	Ur
		JWH-250	Ur
☐ U30		**SYNTHETIC STIMULANTS & CATHINONES**	
		Alpha-PVP	Ur
		Butylone (Bath Salt)	Ur
		Ethylone (Bath Salt)	Ur
		MDPV (Bath Salt)	Ur
		Mephedrone (Bath Salt)	Ur
		Methylone (Bath Salt)	Ur
		Naphyrone (Bath Salt)	Ur
☐ U2		**ALKALOIDS**	
		Cotinine (Nicotine)	Ur
		Mitragynine (Kratom)[M]	Ur
		Lysergic acid diethylamide (LSD)	Ur
		Psilocin (Psilocybin Metabolite)	Ur
		Psilocybin (Magic Mushroom)	Ur
☐ U22	☐ OF13	**SKELETAL MUSCLE RELAXANTS**	
		Carisoprodol	Ur, OF
		Cyclobenzaprine	Ur
		Meprobamate	Ur, OF

SAMPLE TYPE Urine (UR)	SAMPLE TYPE Oral Fluid (OF)	TEST	TYPE
		OPIOIDS: SYNTHETIC	
☐ U11	☐ OF5	Buprenorphine[M]	Ur, OF
☐ U15	☐ OF8	Fentanyls	
		Acetyl Fentanyl	Ur
		Alfentanil	Ur
		Carfentanil	Ur
		Fentanyl[M]	Ur, OF
		Remifentanil Acid	Ur
		Sufentanil	Ur, OF
☐ U20	☐ OF12	Methadone	
		EDDP (Methadone Metabolite)	Ur, OF
		Methadone	Ur, OF
☐ U24	☐ OF15	Opioids and Opiate Analogs	
		Dextromethorphan	Ur
		Meperidine[M]	Ur, OF
		Naloxone	Ur, OF
		Naltrexone	Ur, OF
☐ U28	☐ OF19	Propoxyphene[M]	Ur, OF
☐ U31	☐ OF20	Tapentadol[M]	Ur, OF
☐ U32	☐ OF21	Tramadol[M]	Ur, OF
		OPIATE/OPIOIDS	
☐ U23	☐ OF14	Opiates	
		Codeine	Ur, OF
		Dihydrocodeine	Ur, OF
		Hydrocodone[M]	Ur, OF
		Hydromorphone	Ur, OF
		Morphine	Ur, OF
☐ U25	☐ OF16	Oxycodone	
		Oxycodone[M]	Ur, OF
		Oxymorphone	Ur, OF
☐ U29		**SEDATIVE HYPNOTICS**	
		Zaleplon	Ur
		Zolpidem	Ur
		STIMULANTS	
☐ U3	☐ OF2	Amphetamine	Ur, OF
☐ U21		Ritalin (Methylphenidate)	Ur
☐ U33		**OTHER**	
		Diphenhydramine (Benadryl)	Ur

[M] This test will include parent and/or metabolite of the parent drug.

5 PATIENT PRESCRIBED MEDICATIONS (Please check all that apply)

Including a medication in this section DOES NOT constitute a test request.

☐ Acetaminophen	☐ Duloxetine	☐ Morphine	☐ Risperidone
☐ Alprazolam (Xanax)	☐ Fentanyl	☐ Naloxone	☐ Sativex
☐ Amitriptyline	☐ Fluoxetine	☐ Naltrexone	☐ Secobarbital
☐ Amphetamine	☐ Flunitrazepam	☐ Nordiazepam	☐ Seroquel
☐ Buprenorphine	☐ Flurazepam	☐ Normeperidine	☐ Sertraline
☐ Bupropion	☐ Gabapentin	☐ Nortriptyline	☐ Suboxone
☐ Butabarbital	☐ Haloperidol	☐ Olanzapine	☐ Sufentanil
☐ Butalbital	☐ Hydrocodone	☐ Oxazepam	☐ Tapentadol
☐ Carisoprodol	☐ Hydromorphone	☐ Oxycodone	☐ Tramadol
☐ Citalopram	☐ Imipramine	☐ Oxymorphone	☐ Triazolam
☐ Clonazepam	☐ Ketamine	☐ Paroxetine	☐ Venlafaxine
☐ Clozapine	☐ Lorazepam	☐ PCP	☐ Vilazodone
☐ Codeine	☐ Meperidine	☐ Phenobarbital	☐ Zaleplon
☐ Cyclobenzaprine	☐ Meprobamate	☐ Phentermine	☐ Zolpidem
☐ Despiramine	☐ Methadone	☐ Pregabalin	☐ Zopiclone
☐ Dextromethorphan	☐ Methamphetamine	☐ Pristiq	☐ Other _____
☐ Diazepam	☐ Methylphenidate	☐ Propoxyphene	☐ Other _____
☐ Doxepin	☐ Midazolam	☐ Quetiapine	

An inconsistent result may be reflected on the report if a complete list of patient's medications is not provided

FOR LAB USE ONLY

Date: ____/____/____

Received by: _____ Time: _____ : _____ AM PM

Pt Name _____ Date____/____/____

Donor Intials_____ Date of Birth____/____/____

PEEL AND PLACE ON SPECIMEN CONTAINER

CR50001

PEEL

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 BENIFICIARY NOTICE (ABN)

Your physician may sometimes order laboratory testing that he or she believes to be necessary for your care, but which does not quality 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.

The Office of Inspector General (OIG) takes the position that a physician who orders medically unnecessary test for which Medicare reimbursement is claimed may be subject to civil penalties. Physicians should only order tests they deem medically necessary.