Standardization of Urinalysis Procedure

Manual Procedure

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This guideline is intended for use by a broad range of healthcare professionals, including general practitioners, medical specialists, administrators, policymakers, and nurses.

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I. Principle

A urinalysis is a set of tests that looks at the appearance of your pee (urine) and checks for blood cells, proteins, and other substances. Your provider might use it as a routine screening test or to look for signs of infection, kidney or liver disease, diabetes, or other health conditions.

i. Clinical Reason for Performing the Test

a) **To check your overall health.** A urinalysis might be part of a routine medical exam, pregnancy checkup, or pre-surgery preparation. It might also be used to screen for various disorders, such as diabetes, kidney disease, or liver disease when admitted to a hospital.
b) **To diagnose a medical condition.** A urinalysis might be requested for abdominal pain, back pain, frequent or painful urination, blood in your urine, or other urinary problems. A urinalysis can help diagnose the cause of these signs and symptoms.
c) **To monitor a medical condition.** Suppose you've been diagnosed with a medical condition, such as kidney disease or a urinary tract infection. In that case, your doctor might recommend testing your urine regularly to monitor your condition and treatment.

II. Specimen Requirements

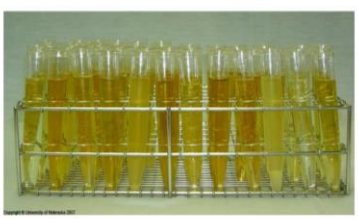
a. Type of Specimen

Types of urine sample

Sample type	Sampling	Purpose
Random specimen	No specific time most common, taken anytime of day	Routine screening, chemical & FEME
Morning sample	First urine in the morning, most concentrated	Pregnancy test, microscopic test
Clean catch midstream	Discard first few ml, collect the rest	Culture
24 hours	All the urine passed during the day and night and next day Ist sample is collected.	used for quantitative and qualitative analysis of substances
Postprandial	2 hours after meal	Determine glucose in diabetic monitoring
Supra-pubic aspired	Needle aspiration	Obtaining sterile urine

b. Volume

- Well-mixed urine
- 12 milliliters (10-15 mL range) routine volume analyzed



ii. *Criteria for Specimen Collection*

Urine is an unstable fluid; it changes composition as soon as it is eliminated through micturition. Accurate collection, storage, and handling are crucial to maintaining the sample's integrity.

A. Urine samples collected from the first void or "morning urine" are considered the best representative for testing. The urine accumulated overnight in the bladder is more concentrated, thus providing an insight into the kidneys' concentrating capacities and allowing for the detection of trace amounts of substances that may not be present in more diluted samples.

B. Other types of urine specimens may be ordered according to specific purposes (randomly, 2-hour postprandial, 24-hour collection). Furthermore, urine should be ideally examined within the first hour after the collection due to the instability of some urinary components (cells, casts, and crystals). If not possible, the sample should be refrigerated at 4 degrees C for up to 24 hours, slowing the decomposition process. Any specimen older than 24 hours cannot be used for urinalysis

iii. *Procedure for Submissions to Central Laboratory*

1. Prepare a Submission Form
   - Include patient details, test requests, and clinical information.
2. Package Specimen
   - Ensure that the specimens are securely packed
3. Transport
   - Send the specimen to the laboratory as soon as possible.

iv. Procedures for Microscopic Examination

Step 1

DETERMINE THE SPECIMEN REQUIREMENTS

In the Test Catalog, use the **Specimen** and **Overview** tabs of each test to identify the following:

- Patient preparation requirements
- Specimen requirements
- Specimen container requirements
- Specimen stability (temperature) requirements
- Collection instructions
- Required forms or special instructions

Whether a preservative must be added at the start of the collection, see the Urine Preservatives Chart for conditions and concentrations of urine preservatives.

Step 2

GIVE URINE COLLECTION INSTRUCTIONS TO THE PATIENT (24-HOUR COLLECTIONS)

If a 24-hour collection is required, print the 24-hour Urine Collection Instructions for the patient.

When you give the instructions and 24-hour collection container to the patient, review:

- Collection duration
- Diet requirements
- Potentially hazardous preservatives in the collection container
- Storage of the specimen until it is returned

Step 3

POUR THE SPECIMEN INTO AN ALIQUOT TUBE OR BOTTLE

Mix well before aliquoting.

- Send urine aliquots in the following leakproof containers only. Other containers could leak and compromise the specimen.
- Some specimens require light protection to ensure specimen integrity. Check the list of Light Protection Tests before packaging your specimen, and use amber containers to prevent analyte degradation due to exposure to light (for 24-hour collections).

		
T068 Urine Tube, 13 mL Standard aliquot tube for random collection.	T313 Urine Container, 60 mL Standard aliquot container for 24-hour collection.	T596 Urine Container, Amber, 60 mL Aliquot tube for 24-hour collections when testing for light-sensitive analytes.

Step 4

LABEL THE SPECIMEN

Specimens must have two person-specific identifiers on the patient label. Person-specific identifiers include:

- Accession number
- Patient's first and last name
- Unique identifying number (for example, medical record number)
- Date of birth

Mislabeled Specimens

Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and the information accompanying the specimen. This information might include a computer system, requisition form, or additional paperwork.

In addition, if a handwritten name and a label are on the container, the information must match exactly. For example, "Rebecca" does not match "Becky." When sufficient or consistent identification is submitted, a new specimen may be required.

Step 5

PACKAGE THE SPECIMEN IN A BIOHAZARD BAG

- ✓ Refrigerate Specimen Bag - pink T027 Ambient Specimen Bag - white T121 Frozen Bag - Yellow
- ✓ Place the tube or container in a Mayo Clinic Laboratories color-coded (temperature-specific) shipping bag.

Biohazard Bag - 12x15 Use if your container is too large for color-coded bags. Mark it Frozen, Refrigerate, or Room Temp (Ambient).

Electronic Clients:

- ➢ Clients who submit electronic orders will have a batch order. Place all specimens for the temperature-specific batch number into one bag. If all the specimens do not fit, use a giant biohazard bag (T043) and indicate the shipping temperature.
- ➢ Do not place multiple batches into one bag.

If you are not using a bag supplied by Mayo Clinic Laboratories:

- ➢ The bag must be leakproof.
- ➢ Absorbent material must be between the primary receptacle (tube/container) and the secondary packaging (bag) that can absorb all the contents.
- ➢ Wrap any breakable tubes individually in bubble wrap.

Step 6

PACKAGE BATCH SHEETS AND FORMS

Folded batch sheet with bar code and delivery address visible

Electronic Clients

Clients who submit electronic orders will have a batch sheet. The bottom of the batch sheet lists the number of pages (for example, 1 of 3). Fold the batch sheets into fourths and place them in the bag's outside pocket. Place them inside the bag with the specimens if there is no pocket. Include all pages in the corresponding bag. The delivery address and bar code, if applicable, must be visible. Do not combine multiple batches into one bag.

Manual Clients

Clients who do not order electronically must include a completed Test Request form with each patient specimen. Fold and insert the forms into the outside pocket of the biohazard bag. Place the forms inside the bag with the specimen if there is no pocket.

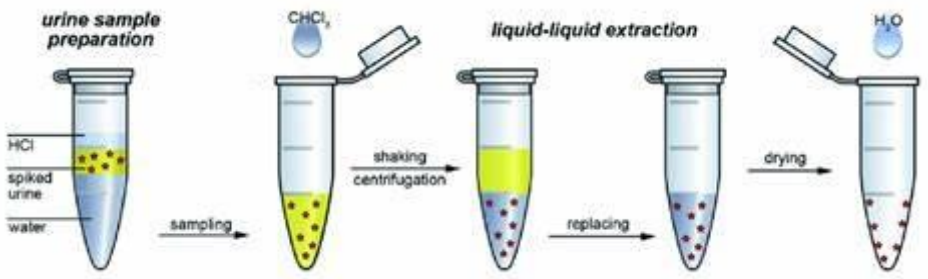
III. Reagents or Media, Supplies, and Equipment

- Alcohol gel
- Gloves
- Apron
- Dipsticks
- Urine sample
- Paper towels

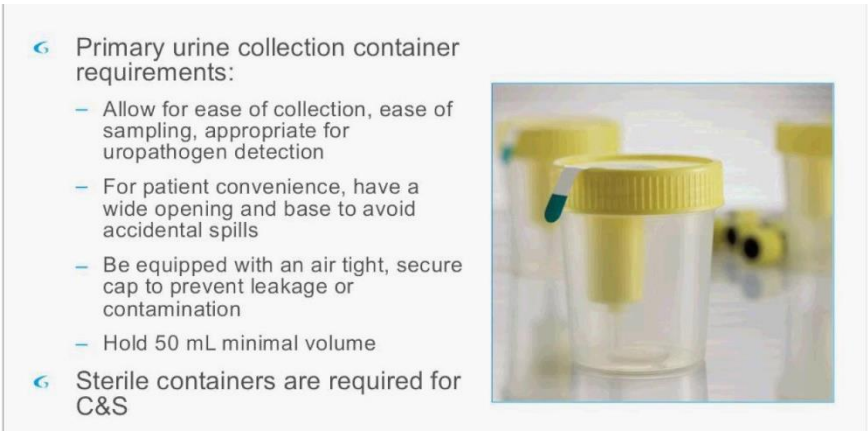
Material Requirement

- Microscope
- Centrifuge
- Slides and cover slides
- Centrifuge tubes 15 ml
- Urine tube
- Urine strips
- Gloves

v. Preparation of Reagents, stains, or other materials used in testing



vi. Storage Requirements



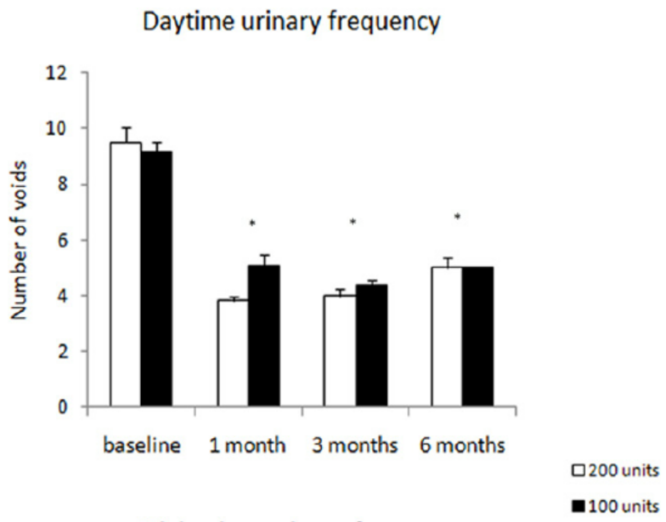
IV. Calibration

- Microscope Calibration
  - Calibrate the microscope using a stage micrometer before the examination.
  - Adjust the lens according to the manufacturer's instructions.

vii. Frequency of Procedure

Urine tests	Result	Abdominal CT scan		Total (*n*)
		Positive (*n*)	Negative (*n*)	
Gross (*n*=8)	Positive	6	2	8
	Negative	27	117	144
Dipstick (*n*=55)	Positive	6	49	55
	Negative	2	87	89
Microscopic (*n*=58)	Positive	11	47	58
	Negative	16	70	86

CT: Computed tomography



viii. Stepwise instructions for preparing and calculating urinalysis specimen

Initial assessment of urine

1. Wash your hands and **don PPE**.

2. Confirm that the patient's details on the sample bottle are correct, including their name, date of birth, and hospital number.

3. Inspect the **color** of the urine:

- **Straw-colored urine** is the normal urine color in a healthy, hydrated individual.
- **Dark, concentrated urine** suggests the individual is dehydrated.
- **Red urine:** can be caused by the presence of blood in the urine (macroscopic haematuria), porphyria, drugs such as rifampicin, and certain foods (e.g., beetroot).
- **Brown urine:** can be caused by the presence of bile pigments (e.g., jaundice) or myoglobin (e.g., rhabdomyolysis) in the urine. Some antimalarial medications, such as chloroquine, also cause brown urine discoloration.

4. Inspect the **clarity** of the urine:

- **Clear urine:** this is normal for healthy, well-hydrated individuals.
- **Cloudy urine with sediment:** may indicate urinary tract infection, renal stones, or high protein content (e.g., nephrotic syndrome).
- **Frothy urine:** typically associated with significant proteinuria (e.g., nephrotic syndrome).

5. Consider opening the sample pot's cap and assessing the urine's **odor**:

- **Offensive odor:** suggestive of urinary tract infection.
- **Sweet odor: suggestive of glycosuria (e.g.,** diabetes mellitus).
- Assessment of urinary odor is **rarely performed** in practice.

V. Quality Control

QC Format	Pros	Cons
Dipper Style (Multi-use) 	• Simulates patient sample testing by utilizing a full immersion of the test strip into the control fluid • Reagent pads become fully saturated • QC method in full compliance with CLIA regulations	• Requires a large volume of control fluid to execute a test • Increased risk of contamination with repeated use • Increased risk of chemicals from reagent pads leading to erroneous QC results
Dropper Style 	• Requires very little volume to execute a test • Minimal risk of contamination from repeated use • No risk of chemical leaching from reagent pads leading to erroneous QC results	• Potential conflict with CLIA regulations as dropping does not represent the method by which patient samples are tested • Reagent pads are not as easily saturated and may lead to erroneous QC results
Dipper Style (Single-use) 	• Simulates patient sample testing by utilizing a full immersion of the test strip into the control fluid • Reagent pads become fully saturated • No risk of contamination from repeated use • No risk of chemical leaching from reagent pads leading to erroneous QC results • QC method in full compliance with CLIA regulations	• Unitized format may be less cost-effective on a per test basis than multi-use dipper and dropper style QC formats

VI. STEP-BY-STEP INSTRUCTIONS

Interpretation of dipstick results

The following tests are ordered by the time at which the reagent square should be interpreted.

1. Glucose

   Glucose is a water-soluble sugar molecule, and its presence in the urine is known as glycosuria:

- Time at which the reagent square should be interpreted: 30 seconds
- The absence of glucose in the urine is normal.
- Causes of glycosuria include diabetes mellitus, renal tubular disease, and some diabetic medications (e.g., SGLT2 inhibitors).

2. Bilirubin

   Conjugated bilirubin is a water-soluble yellow pigment:

- Time at which the reagent square should be interpreted: 30 seconds
- The absence of bilirubin in the urine is normal.
- The presence of bilirubin in the urine suggests increased serum levels of conjugated bilirubin, which can occur in conditions such as biliary obstruction (e.g., pancreatic cancer).

3. Ketones

   Ketones are a breakdown product of fatty acid metabolism:

- Time at which the reagent square should be interpreted: 40 seconds
- The absence of ketones in the urine is normal.
- The presence of ketones in the urine suggests increased fatty acid metabolism, which occurs during starvation and in conditions such as diabetic ketoacidosis.

4. Specific gravity

   The specific gravity reagent square indicates the amount of solute dissolved in the urine:

- Normal range: 1.002 – 1.035 mOsm/kg
- Time at which the reagent square should be interpreted: 45 seconds
- Causes of low specific gravity include conditions that produce dilute urine, such as diabetes insipidus and acute tubular necrosis.
- Causes of raised specific gravity include dehydration, glycosuria (e.g., diabetes mellitus), and proteinuria (e.g., nephrotic syndrome).

5. pH

   The pH reagent square represents the acidity of the urine:

- Normal range: 4.5 – 8
- Time at which the reagent square should be interpreted: 60 seconds
- Causes of low urinary pH include starvation, diabetic ketoacidosis, and other conditions that cause metabolic acidosis (e.g., sepsis).
- Causes of raised urinary pH include urinary tract infections, conditions that cause metabolic alkalosis (e.g., vomiting), and medications (e.g., diuretics).

6. Blood

   The blood reagent square indicates the number of red blood cells, hemoglobin, and myoglobin in the urine:

- Time at which the reagent square should be interpreted: 60 seconds
- The absence of red blood cells, hemoglobin, and myoglobin in the urine is normal.
- The presence of red blood cells, hemoglobin, and myoglobin in the urine may indicate urinary tract infection, renal stones, injury to the urinary tract, myoglobinuria (rhabdomyolysis), nephritic syndrome, and urinary tract malignancy.

7. Protein

   The protein reagent square indicates the level of protein present in the urine (proteinuria):

- Time at which the reagent square should be interpreted: 60 seconds
- The absence of protein in the urine is normal.
- Causes of proteinuria include nephrotic syndrome and chronic kidney disease.

8. Nitrites

   Nitrites are a breakdown product of gram-negative organisms such as E.Coli:

- Time at which the reagent square should be interpreted: 60 seconds
- The absence of nitrites in the urine is normal.
- The presence of nitrites in the urine suggests a urinary tract infection.

9. Urobilinogen

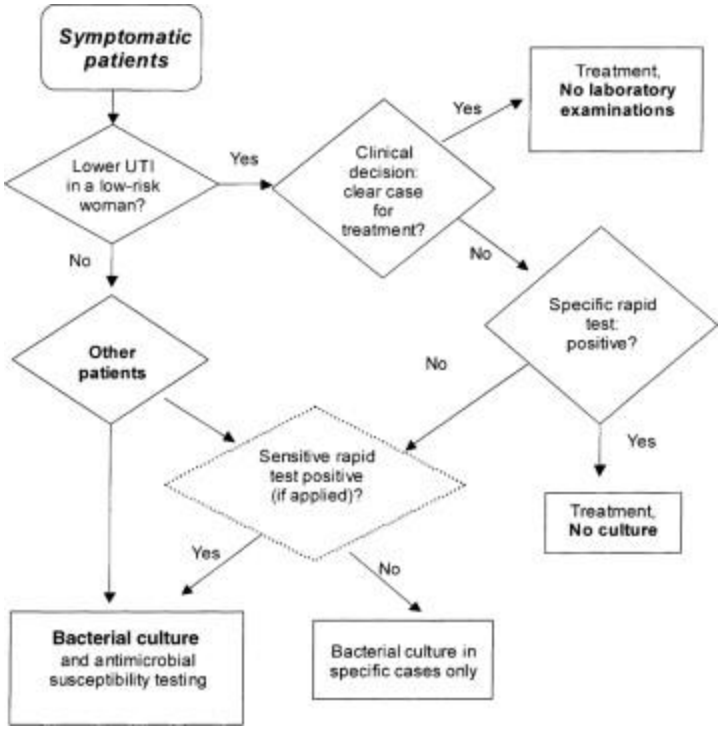
   Urobilinogen is a byproduct of bilirubin breakdown in the intestine, and it is normally excreted in the urine:

- Normal range: 0.2 – 1.0 mg/dL
- Time at which the reagent square should be interpreted: 60 seconds
- The presence of increased levels of urobilinogen in the urine can be caused by hemolysis (e.g., hemolytic anemia, malaria).
- Low levels of urobilinogen can be caused by biliary obstruction.

10. Leukocyte esterase

Leukocyte esterase is an enzyme produced by neutrophils and therefore, when positive, it indicates the presence of white cells in the urine:

- Time at which the reagent square should be interpreted: 2 minutes
- A negative leukocyte esterase test is normal.
- Causes of a positive leukocyte esterase include urinary tract infection and any condition that could result in haematuria.



$$\text{mg proteins/100 mL in Urine} = \frac{\text{A (unknown)}}{\text{A (standard)}} \text{X25}$$

Normal = 0.05 to 0.1 g/24 hours

labpedia.net

VII. Calculations

Method	Formula
Measured 1 h urinary creatinine clearance	Urinary volume × urinary creatinine concentration × 1.73/ plasma creatinine × 60 min × BSA[a]
Cockcroft–Gault	(140 − age) × body weight × 1.73 (×0.85 if female)/serum creatinine × 72×BSA[a]
MDRD	$170 \times \text{creatinine}^{-0.999} + \text{age}^{-0.176} \times (0.762$ if female) × (1.180 if black) × serum $\text{urea}^{-0.170} \times \text{albumin}^{0.318}$
Simplified MDRD	$186 \times \text{creatinine}^{-1.154} \times \text{age}^{-0.203} \times$ (1.212 if black) × (0.742 if female)

[a]BSA = body surface area.

VIII. Reporting Results

☐**UA CHEMSTRIP SCREEN**

Color _____ Clarity _____

Specific Gravity	☐1.000	☐1.005	☐1.010	☐1.015	☐1.020	☐1.025	☐1.030	1.005–1.030
pH	☐5	☐6	☐7	☐8	☐9			5–8
Leukocyte	☐negative		☐trace		☐1+*	☐2+		Negative
Nitrite	☐negative		☐positive					Negative
Protein	☐negative		☐trace	☐1+	☐2+	☐3+		Negative
Glucose	☐normal		☐50**	☐100	☐250	☐500	☐1000	Normal
Ketone	☐negative		☐1+	☐2+	☐3+			Negative
Urobilinogen	☐normal		☐01	☐04	☐08	☐012		Normal
Bilirubin	☐negative		☐1+	☐2+	☐3+			Negative
Blood	☐negative		☐trace	☐1+(about 50 #)		☐2+(about 250)		Normal

☐**MICROSCOPIC URINALYSIS** (performed by technologists, MD or NP only)

WBC _____/hpf (<5/hpf) Bacteria _____Negative

RBC _____/hpf (<5/hpf) Casts _____/lpf Type _____

Epi _____/lpf Crystals _____

*arbitrary units based on the sensitivity of the reagent strip (see manufacturer's insert)

**mg/dL

#intact red blood cells/microliter

Procedures for Reporting Abnormal Results

1. Immediately notify the responsible clinician of any critical or abnormal findings.
2. Document the abnormal results in the laboratory information (LIS)
3. Include a clear description of the abnormal findings and their potential implications.
4. Follow the laboratory's protocol for confirming abnormal results, which may include re-testing or using additional methods.

Reporting Format

- Patient information (*name, ID number, date of birth, collection date and time*)
- Test details (*type of test performed, specimen type*)
- Results
- Comments
- Signature of the technologists performing the test

Procedure notes

- Ensure all results are double-checked for accuracy before reporting.
- Maintain confidentiality and ensure that reports are distributed securely.

Special Precautions

1. Biohazard safety

Handle all specimens and slides as potentially infectious.

2. Equipment safety

Ensure proper use of microscopes and staining equipment to prevent accidents.

3. Regulatory compliance

Adhere to local and national regulations regarding laboratory reporting.

Possible Sources of Error

1. Preparation errors
2. Staining errors
3. Microscopic errors
4. Sample contamination

Answer to Common Problems

- Gout is described as? - Answer crystal-induced synovitis of a heterogeneous nature.
- Sperm morphology in a normal sample should be? - Answer >30% normal
- The procedure for the removal of fluid from synovial joints is called? - Answer arthrocentesis Intracranial
- Pressure is defined as? - Answer the pressure inside the skull.
- Lumbar puncture is synonymous with? - Answer spinal tap:
- A fluid within the body that possesses serum-like features whose consistency is more thin or watery than thick or viscous describes what? - Answer serous fluid
- The primary site of CSF formation is? - Answer choroid plexus
- A medical procedure to irrigate and remove fluid contained in the peritoneal cavity for the purpose of examination is called? - Answer peritoneal lavage
- Synovial fluid is described as? - Answer ultrafiltrate of plasma to which proteins and proteoglycans are added by fibroblast-like synoviocytes in the lining layers.

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