

1 **Clinical Practice Guideline:** **In-Office Clinical Laboratory Services**

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3 **Date of Implementation:** **April 19, 2012**

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5 **Product:** **Specialty**

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8 **GUIDELINES**

9 American Specialty Health, Inc. (ASH) considers clinical laboratory services performed
 10 by a qualified healthcare professional as medically necessary when meeting all of the
 11 following criteria:

- 12 • The history and physical exam findings substantiate the working diagnosis and the
 13 need for further evaluation through laboratory testing;
- 14 • The clinical laboratory procedure is known to be reliable and reproducible; and
- 15 • The procedure is CLIA (Clinical Laboratory Improvement Amendments) waived.

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17 **DESCRIPTION AND BACKGROUND**

18 A variety of clinical laboratory services are performed by practitioners in the office.
 19 Dipstick urinalysis, for example, utilizes a dipstick or tablet reagent to test for a variety of
 20 constituents including ketones and leukocytes. This procedure may be done manually or
 21 via automation and microscopic review may (CPT codes 81000 and 81001) or may not
 22 (CPT code 81002) be included.

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24 Venipuncture and finger sticks are other examples of clinical laboratory services, which
 25 provide blood samples for analyses such as prothrombin time, glucose or lipid levels.

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27 All laboratory services should be supported by the appropriate ICD codes at the primary
 28 and secondary level. The diagnosis must be documented for the procedure to be considered
 29 for reimbursement. In addition, the procedure must be reasonable and necessary for that
 30 diagnosis. Documentation within the medical record must support the necessity for the
 31 test(s) performed for each date of service.

32

33 Handling or conveying laboratory specimens is an adjunct to basic services provided.
 34 Handling and/or conveyance of a specimen for transfer may be from the physician’s office
 35 to a laboratory (CPT code 99000). Alternatively, the specimen may be processed for
 36 transfer from the patient in a location other than the physician’s office to a laboratory (CPT
 37 code 99001).

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39 ASH expects all practitioners that perform laboratory services to follow Clinical
 40 Laboratory Improvement Amendments (CLIA) requirements.

- 1 **The following table lists CPT codes that may be medically necessary upon meeting**
 2 **the criteria listed above.**

CPT® Code	CPT® Code Description
36415	Collection of venous blood by venipuncture
36416	Collection of capillary blood specimen (e.g., finger, heel, ear stick)
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81020	Urinalysis, two or three glass test
81025	Urine pregnancy test, by visual color comparison methods
82465	Cholesterol, serum or whole blood, total
82947	Glucose; quantitative, blood (except reagent strip)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
84550	Uric acid; blood
85013	Blood count; spun microhematocrit
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85060	Blood smear, peripheral, interpretation by physician with written report
85610	Prothrombin time
87426	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay

CPT® Code	CPT® Code Description
	[FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
99000	Handling and/or conveyance of specimen for transfer from the office to a laboratory
99001	Handling and/or conveyance of specimen for transfer from the patient in other than an office to a laboratory (distance may be indicated)

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2 **DOCUMENTATION REQUIREMENTS TO SUBSTANTIATE MEDICAL**
3 **NECESSITY**

4 “Medically necessary” or “medical necessity” shall mean health care services that a
5 Healthcare Provider, exercising prudent clinical judgment, would provide to a patient for
6 the purpose of evaluating, diagnosing, or treating an illness, injury, disease or its
7 symptoms, and that are (a) in accordance with generally accepted standards of medical
8 practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration;
9 and considered effective for the patient’s illness, injury, or disease; and (c) not primarily
10 for the convenience of the patient or healthcare provider, and not more costly than an
11 alternative service or sequence of services at least as likely to produce equivalent
12 therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness,
13 injury, or disease.

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15 The patient’s medical records should document the practitioner’s clinical rationale for
16 performing/ordering the specific laboratory procedures, as well as, their impact on the
17 treatment plan for the patient. In addition, copies of all laboratory reports must be included
18 in the patient’s medical records.

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20 **PRACTITIONER SCOPE AND TRAINING**

21 Practitioners should practice only in the areas in which they are competent based on their
22 education training and experience. Levels of education, experience, and proficiency may
23 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
24 to determine if they have the knowledge and skills necessary to perform such services and
25 whether the services are within their scope of practice.

26
27 It is best practice for the practitioner to appropriately render services to a patient only if
28 they are trained to competency, equally skilled, and adequately competent to deliver a

1 service compared to others trained to perform the same procedure. If the service would be
2 most competently delivered by another health care practitioner who has more skill and
3 training, it would be best practice to refer the patient to the more expert practitioner.
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5 Best practice can be defined as a clinical, scientific, or professional technique, method, or
6 process that is typically evidence-based and consensus driven and is recognized by a
7 majority of professionals in a particular field as more effective at delivering a particular
8 outcome than any other practice (Joint Commission International Accreditation Standards
9 for Hospitals, 2020).
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11 Depending on the practitioner’s scope of practice, training, and experience, a patient’s
12 condition and/or symptoms during examination or the course of treatment may indicate the
13 need for referral to another practitioner or even emergency care. In such cases it is essential
14 for the practitioner to refer the patient for appropriate co-management (e.g., to their primary
15 care physician) or if immediate emergency care is warranted, to contact 911 as appropriate.
16 See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for
17 information.
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19 **References**

20 American Medical Association. (current year). *Current Procedural Terminology (CPT)*
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23 Centers for Disease Control and Prevention (CDC). (2018) About CLIA. Retrieved August
24 24, 2023 from <https://www.cdc.gov/clia/>
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26 Joint Commission International. (2020). *Joint Commission International Accreditation*
27 *Standards for Hospitals (7th ed.)*: Joint Commission Resources