

(2) MEETS THE EXCEPTION REQUIREMENTS IN REGULATIONS ADOPTED BY THE SECRETARY PURSUANT TO THIS SUBTITLE.

(c) [(1)] For the purposes of this section, "limited MEDICAL laboratory TESTS OR examinations" means simple MEDICAL laboratory [examinations and] procedures [that] AS DEFINED IN REGULATIONS ADOPTED BY THE SECRETARY PURSUANT TO THIS SUBTITLE [have an insignificant risk of an erroneous result].

[(2) "Limited laboratory examinations" includes, but is not limited to:

- (i) 1. Dermatophyte screen;
2. Dipstick glucose;
3. Dipstick urinalysis;
4. Gram stain;
5. Group "A" streptococcal screen;
6. Hematocrit;
7. Hemoglobin;
8. Infectious mononucleosis slide or card test;
9. Microscopic urinalysis;
10. Occult blood;
11. Pinworms;
12. Potassium hydroxide skin preparations;
13. Rheumatoid factor slide agglutination test;
14. Sickle-cell screen;
15. Urine bacteria colony count;
16. Urine pregnancy slide test; and
17. Wet mounts; or

(ii) 1. Examinations and procedures that have been approved by the Food and Drug Administration for home use;

2. Methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; and

3. Examinations and procedures that the Secretary determines pose no reasonable risk of harm to the patient if performed incorrectly.]

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To qualify for a [permit] LICENSE, an applicant shall PROVIDE EVIDENCE TO satisfy the Secretary that the medical laboratory [to be operated, represented, or