§ 571. Definitions. As used in this title:

1. "Clinical laboratory" means a facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition or for identification purposes. Such examinations shall include procedures to determine, measure or otherwise describe the presence or absence of various substances, components or organisms in the human body. The term clinical laboratory shall not include any facility or activity specifically excluded by section five hundred seventy-nine of this title.

2. "Blood bank" means a facility for the collection, processing, storage and/or distribution of human blood, blood components or blood derivatives, but shall not mean a source plasma donation center.

2-a. "Source plasma donation center" means a facility where source plasma is collected by plasmapheresis. "Source plasma" means the fluid portion of human blood collected by plasmapheresis and intended as source material for plasma protein therapies. "Source plasma donation center" shall not include single donor plasma products intended for intravenous use.

2-b. "Plasmapheresis" means a procedure by which, during a single visit to the facility, blood is removed from an individual, the source plasma separated from the formed elements, and at least the red blood cells are returned to the donor.

3. "Reference system" means a system of assessment of methods, procedures and materials of clinical laboratories and blood banks, including, but not limited to, ongoing validation which may include direct testing and experimentation by the department of such methods, procedures and materials, the distribution of standards and guidelines, inspection of facilities, periodic submission of test specimens for examination, and research conducted by the department that involves the

study of new or existing methods, procedures and materials related to the quality of clinical laboratory medicine.

4. "Director" means the person who is responsible for administration of the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.

5. "Waived test" means a clinical laboratory test that has been designated as a waived test or is otherwise subject to certificate of waiver requirements pursuant to the federal clinical laboratory improvement act of nineteen hundred eighty-eight, as amended.

* 6. "Qualified health care professional" means a physician, dentist, podiatrist, optometrist performing a clinical laboratory test that does not use an invasive modality as defined in section seventy-one hundred one of the education law, pharmacist administering COVID-19 and influenza tests pursuant to subdivision seven of section sixty-eight hundred one of the education law, physician assistant, specialist assistant, nurse practitioner, or midwife, who is licensed and registered with the state education department.

* NB Effective until July 1, 2030

* 6. "Qualified health care professional" means a physician, dentist, podiatrist, optometrist performing a clinical laboratory test that does not use an invasive modality as defined in section seventy-one hundred one of the education law, physician assistant, specialist assistant, nurse practitioner, or midwife, who is licensed and registered with the state education department.

* NB Effective July 1, 2030

7. "Provider-performed microscopy procedure" means a procedure performed by a qualified health care professional acting within the scope of his or her licensed profession, which has been designated as a provider-performed microscopy procedure pursuant to the federal clinical laboratory improvement act of nineteen hundred eighty-eight, as amended.

8. "Laboratory test registrant" means a person, partnership, corporation, or other entity holding a valid certificate of registration

to perform one or more waived tests or provider-performed microscopy procedures pursuant to section five hundred seventy-nine of this title.