5101:3-11-01 <u>Definitions: Independent independent laboratory, portable x-ray supplier, and independent diagnostic testing facility (IDTF), and mammography supplier: definitions.</u>

## (A) Independent laboratory.

- (A) "Independent laboratory" means a facility established for the biological, microbiological, immunological, immunohematological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials of the human body for the purpose of providing obtaining information for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of an individual's the health of, human beings. An "independent laboratory" is a facility that It is independent of the an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. A laboratory under the ownership and direction of a physician or physician group, such as a pathologist(s), is considered to be an independent laboratory if the physician holds himself or herself and the facilities of his or her office out to other physicians as being it is represented to other physicians that both the physician-owner(s)/director(s) and the facility are available for the performance of laboratory procedures. Facilities that only collecting or preparing collect or prepare specimens or that function only serving as a mailing service and do not performing perform testing are not considered to be laboratories.
- (B) Independent portable x-ray supplier.
- (B) portable "Portable x-ray supplier" means an entity established for the performance provision of diagnostic x-ray procedures when the services are provided in a patient's consumer's place of residence.
- (C) Independent diagnostic testing facility.
- (1)(C) "Independent diagnostic testing facility (IDTF)" means a facility or an entity established for the performance of diagnostic tests that are performed conducted by licensed or certified nonphysician personnel under appropriate physician supervision. The facility An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner, and in all cases must comply with applicable state law. The "independent diagnostic testing facility" must meet all standards and provide services in accordance with 42 C.F.R. 410.33 (October 1, 2005). An "independent diagnostic testing facility" is a facility that It is independent of the an attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital. An independent A diagnostic testing facility under the ownership and direction of a physician or physician group is considered to be an independent diagnostic testing facility if the physician holds himself or herself and the facilities of his or her office out to other physicians as being it is represented to other physicians that both the physician-owner(s)/director(s) and the facility are

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available for the performance of diagnostic tests.

(2)(D) An "independent mammography "Mammography supplier" means a facility or an entity established solely for the single purpose of performing provision of mammography services. An "independent mammography supplier" is a facility or entity that is independent of the attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital and meets the certification requirements of Section 354 of the Public Health Services Act as implemented by 21 C.F.R. (April 1, 2005) part 900, subpart B and has a valid certificate that has been issued by the U.S. food and drug administration (FDA). Under For billing and payment purposes within the Ohio medicaid program, all independent a mammography suppliers are considered supplier is treated as an independent diagnostic testing facilities facility.

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Certification

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