University of California, Davis Health System, Sacramento Department of Pathology and Laboratory Medicine

REFERRAL LABORATORY ELIGIBILITY AND SELECTION

Administrative Procedure 500.A

PURPOSE:

Outline the process for selecting referral laboratories, and ensuring their and our compliance with State and Federal laws, JCAHO and College of American Pathologist requirements.

POLICY:

The Department of Pathology and Laboratory Medicine contracts for clinical and anatomic laboratory services including intermediate processing such as histopathology/cytology preparation and nucleic acid sequencing from Reference Laboratories which comply with all regulatory requirements and meet rigorous departmental standards.

PROCEDURE:

- 1. Pursuant to Federal Regulations and California law, all laboratories to which UCDHS refers testing must be licensed by the State of California, accredited by CAP or certified by CMS, or meet equivalent requirements as determined by CMS, and CAP or JCAHO.
- 2. Testing to be used for patient management decisions for patients on research protocols shall be referred the to a CLIA-certified research laboratory, or one meet equivalent requirements as determined by CMS.
- 3. Testing must be referred to a laboratory accredited by CAP for disciplines not covered by CLIA (e.g., histology).
- 4. For non-U.S. laboratories, whenever possible, referral specimens shall be sent to a laboratory accredited by CAP; accredited to an established international standard from a recognized organization; or certified by an appropriate government agency.
- 5. A list of laboratories meeting these requirements to which UCDHS refers laboratory work is maintained by SARC and Client Services, and is available for reference.
- 6. All requests to add a reference laboratory not on the list will be submitted to the Chief Administrative Officer and Test Utilization Committee for review and verification of eligibility.
- 7. Reference laboratories are selected based on the following criteria:

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- a. Test availability,
- b. Test methodology,
- c. Quality of testing performed,
- d. Turnaround time,
- e. Reporting and system interfaces,
- f. Consultative services,
- g. Transport availability
- h. Cost
- 5. UCDHS clinician referral complaints and problems will be forwarded for review and follow up to the Laboratory Director, Clinical Pathology Director, or Anatomic Pathology Director, and Chief Administrative Officer.
- 6. The Laboratory Director (Chair or CP/AP Director) or his/her designee is responsible for the selection of all reference laboratories and monitoring of the testing quality provided by them.

REFERENCE:

Code of Federal Regulations, Title 42 CFR 411.1, Title 42 CFR 411 Subpart J.

PROCEDURE HISTORY:

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Date	Written	Revision	Approved Date	Approved By
1/0.5	Revised By		1/07	
4/86	R. Lowe	New	4/86	M. Gardner
2/93	R. Lowe	Revision	2/93	R. Cardiff
3/93	S. Hamill	Revision	3/93	R. Cardiff
7/94	D. O'Sullivan	Revision	7/94	R. Cardiff
4/96	D. O'Sullivan	Revision	4/96	R. Cardiff
10/96	D. O'Sullivan	Revision	10/96	R. Green
12/96	D. O'Sullivan	Revision	12/96	R. Green
11/97	D. O'Sullivan	Annual Review	11/97	R. Green
11/98	D. O'Sullivan	Annual Review	11/98	R. Green
5/00	D. O'Sullivan	Annual Review	5/00	R. Green
5/00	D. O'Sullivan	Annual Review	5/00	R. Green
9/01	D. Brown	Revision	9/01	R. Green
10/02	C. White	Annual Review	10/02	E. Larkin
10/03	D. O'Sullivan	Annual Review	10/03	E. Larkin
2/04	D. O'Sullivan	Annual Review	2/04	R. Green
10/04	D. O'Sullivan	Revision	10/04	R. Green
9/06	D. Wright	Revision	09/06	R. Green
07/07	D. Wright	Reviewed	07/07	R. Green
06/08	C. White	Revised	06/08	R. Green
06/09	D. Wright	Annual Review	06/09	L. Howell
05/10	D. Wright	Revised	5/10	L. Howell
9/1/10	D. Wright	Revised	9/10	L. Howell
11/12	E. Brennan	Revised	11/12	L. Howell