



APPENDIX A
Representative Tc 99m LeuTech® Images

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IMAGE 1: The “Appendicitis Zone”
Study 98-004, Patient J-22, Male



Anterior
53 minutes

- Nuclear medicine images of patients with appendicitis who have been administered Tc 99m LeuTech® typically demonstrate focal uptake within the “appendicitis zone”. The “appendicitis zone” is defined as the wide anatomic area centered about the right lower quadrant, as shown in this negative image.

IMAGE 2: Typical Positive Appendicitis Image
Study 98-004, Patient B-18, Male



Anterior
56 minutes

This image is a typical example of a Tc 99m LeuTech[®] scan that is positive for appendicitis. There is focal, asymmetrical, abnormal uptake within the appendicitis zone. Uptake was visible early in the imaging sequence and intensified over time.

The guidelines provided to investigators for identifying a Tc 99m LeuTech image as positive for appendicitis included the following points:

- Persistent, abnormal uptake within the appendicitis zone, of any intensity level, any pattern or any extent.
- Initial uptake is usually visible within the first 60 minutes of imaging.
- The intensity of the uptake typically remains constant or intensifies over time.

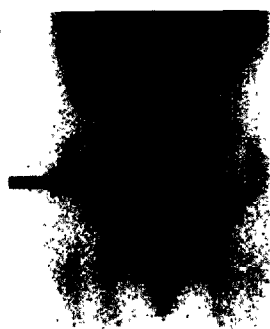
IMAGE 3: Typical Negative Appendicitis Image
Study 98-004, Patient A-9, Female



Anterior
48 minutes

This image is a typical example of a Tc 99m LeuTech[®] scan that is negative for appendicitis. There is no abnormal uptake within the appendicitis zone and no asymmetry between the right lower quadrant and the left lower quadrant.

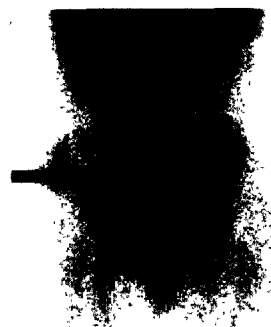
IMAGE 4: Case Study #1, Positive Appendicitis Image
Abnormal Focal Uptake Pattern
Study 98-004, Patient A-08, Female



Anterior
61 minutes



Right Anterior Oblique
66 minutes



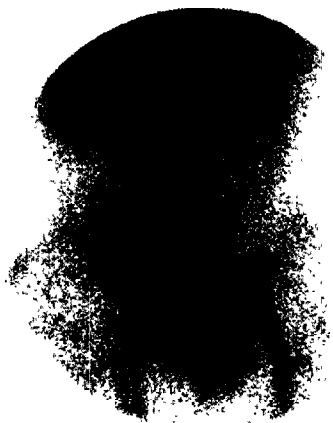
Left Anterior Oblique
70 minutes

These images are from a 44 year-old female presenting with right lower quadrant abdominal pain. The patient presented with an elevated WBC count, a temperature less than 101° F, atypical history and an atypical physical examination. The initial patient management plan was to admit to the hospital for clinical observation. The Tc 99m LeuTech® scan was positive for appendicitis with abnormal, focal uptake apparent on the anterior image and both the left and right anterior oblique images. Following the positive scan interpretation, emergency laparotomy was performed. Surgical and histopathological findings indicated perforated appendicitis.

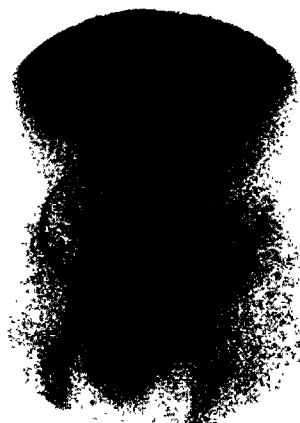
IMAGE 5: Case Study #2, Positive Appendicitis Image
Abnormal Diffuse Uptake Pattern
Study 98-004, Patient A-11, Male



Anterior 53 minutes



Right Anterior Oblique 65 minutes



Left Anterior Oblique 69 minutes

This image is an example of a diffuse uptake pattern that was positive for acute appendicitis. The patient was a 35 year-old male who presented with atypical right lower quadrant abdominal pain, atypical history, an elevated WBC count and a temperature less than 101° F. The initial patient management plan was to send the patient home. The Tc 99m LeuTech® scan was positive for appendicitis with abnormal, diffuse uptake apparent on the anterior image and both the left and right anterior oblique images. Following the positive scan interpretation, the patient was taken to surgery. Surgical findings indicated a perforated appendix. The Tc 99m LeuTech® scan had a significant impact on management of the patient: surgical treatment was accelerated and potential peritonitis was avoided.

IMAGE 6: Case Study #3, Negative Appendicitis Image
Normal Uterine Uptake Pattern
Study 98-004, Patient A-35, Female



Anterior
51 minutes

This Tc99m LeuTech image was from a 40 year old female who presented with atypical right lower quadrant abdominal pain. The initial patient management plan was to admit for clinical observation. The Tc99m LeuTech scan demonstrated normal uterine blush above the bladder, but was negative for appendicitis. The patient was sent home, reported resolution of abdominal pain at 2 week follow up and had a final diagnosis of abdominal pain of unknown etiology.

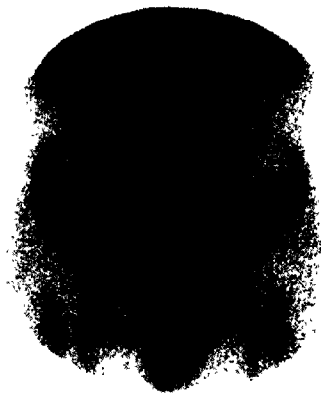
IMAGE 7: Case Study #4, Patient Management Change
Prevention of Unnecessary Laparotomy
Study 98-004, Patient C-04, Female



Anterior
63 minutes

This image is from a 26 year-old female presenting with right lower quadrant abdominal pain that had increased in intensity over the preceding days, a fever and an elevated WBC count. The physical examination was consistent with a diagnosis of acute appendicitis; however, the history and symptoms were atypical (absence of periumbilical pain migrating to the right lower quadrant). The initial patient management plan was to perform surgery. The Tc 99m LeuTech[®] scan was negative for appendicitis. Following the negative scan interpretation, the patient management plan was changed and the patient was admitted to the hospital for clinical observation. Surgery was not performed. The patient was discharged from the hospital and had a negative two-week follow up and a negative final diagnosis for appendicitis.

**IMAGE 8: Case Study #5, Patient Management Change
Avoided Delayed Treatment and Potential Peritonitis
Study 98-004, Patient D-13, Male**



Anterior
46 minutes

This Tc 99m LeuTech[®] scan is from a 27 year-old male who presented with right lower quadrant abdominal pain. He had an atypical history and an atypical physical exam, a temperature less than 101° F and a normal WBC count. The initial patient management plan was to discharge the patient and observe at home. The Tc 99m LeuTech[®] scan was positive for appendicitis, with a diffuse uptake pattern. Following the positive scan interpretation, an emergency laparotomy was performed. Surgical findings indicated perforated appendicitis.

**IMAGE 9, Case Study #6, Patient Management Change
Avoided Delayed Treatment and Admission for Observation
Study 98-004, Patient A-29, Female**



4 minutes



8 minutes



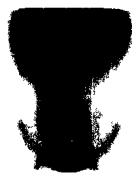
12 minutes



16 minutes



20 minutes



24 minutes



28 minutes



32 minutes

Anterior Dynamic Images

Whole Body Scan



This series of Tc 99m LeuTech[®] scans was performed in a 17 year-old female who presented with right lower quadrant (RLQ) abdominal pain. The medical history and physical examination were equivocal for appendicitis. The initial patient management plan was to admit and observe. Anterior dynamic images obtained over the first 32 minutes after injection demonstrate abnormal accumulation in the right lower quadrant with additional activity tracking along the right colon/paracolic gutter area suggesting perforated appendicitis. Following the positive scan interpretation, emergency laparotomy was performed. Surgical findings indicated a perforated appendix.