QUANTA Lite™ Actin IgG ELISA  708785

For In Vitro Diagnostic Use
CLIA Complexity: High

Principles of the Procedure

Purified F-actin antigen is bound to the wells of a polystyrene microwell plate under conditions that will preserve the antigen in its native state. Pre-diluted controls and diluted patient sera are added to separate wells, allowing any actin antibodies present to bind to the immobilized antigen. Unbound sample is washed away and an enzyme labeled anti-human IgG conjugate is added to each well. A second incubation allows the enzyme labeled anti-human IgG to bind to any patient antibodies, which have become attached to the microwells. After washing away any unbound enzyme labeled anti-human IgG, the remaining enzyme activity is measured by adding a chromogenic substrate and measuring the intensity of the color that develops. The assay can be evaluated spectrophotometrically by measuring and comparing the color intensity that develops in the patient wells with the color in the control wells.

QUANTA Lite™ Actin IgG is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of IgG antibodies to the actin component of smooth muscle in human serum. The presence of Actin antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of autoimmune liver diseases such as autoimmune hepatitis (AIH) and primary biliary cirrhosis (PBC).

Anti-actin autoantibodies are the main component of what have been called smooth muscle antibodies (ASMA). These antibodies display specificity towards the actin component of the cytoskeleton\(^1,2\) and are traditionally detected by indirect immunofluorescence utilizing thin sections of rodent liver, kidney or stomach as substrate.\(^1,3\) Anti-actin antibodies are found in 52-85% of patients with AIH or chronic active hepatitis (CAH) and in 22% of patients with primary biliary cirrhosis (PBC).\(^4,5\) Anti-actin antibodies have been reported, usually in low titers, in 3-18% of sera from the general healthy population.\(^6\)

Immunofluorescent procedures for detection of actin or smooth muscle antibodies are subjective, with assay performance dependent on the type of tissue used, conjugate specificity, strength of the microscope system used to read the result as well as the experience of the observer. Newer ELISA methods first reported in the mid 1980's to early 1990's\(^4,5,7,8\) have the potential for superior as well as more standardized and automatable performance. It has been reported that anti-smooth muscle specificity for actin is found primarily in patients with CAH; whereas, in viral infections such as infectious mononucleosis, viral hepatitis, measles and mumps, that anti-smooth muscle reactivity is due to reactivity to non-actin cytoplasmic antigens.\(^1,2,3,9,10\)

Smooth muscle antibodies and anti-nuclear antibodies are the immunoserological hallmarks of type 1 autoimmune hepatitis.\(^11\) Smooth muscle antibodies are directed against several components, the most important of which is actin but immunofluorescence can also detect antibodies to tubulin and intermediate filaments.\(^12\)

Recent studies have suggested that it is the anti-actin antibodies that have specificity for autoimmune liver disease and they have been advocated as better markers for autoimmune hepatitis than anti-smooth muscle.\(^12,13,14\) In fact, the designation “anti-actin hepatitis” has been used to describe this condition.\(^15\) Czaia et al.\(^14\) have shown that anti-actin antibodies were present in 73 of 99 (74%) patients with type 1 autoimmune hepatitis and in 0 of 83 healthy blood donors and in 3-15% of patients with other types of chronic hepatitis. From this same study it was determined that nearly all (99%) of actin positive patients were also smooth muscle antibody positive while 46% of the actin negative group had smooth muscle reactivity. Anti-actin positive patients were more prone to be unresponsive to corticosteroid therapy (16% vs. 4%) and were more prone to suffer liver failure (20% vs. 4%).\(^14\)

Reagents

1. Polystyrene microwell ELISA plate coated with a purified Actin antigen (12-1 x 8 wells), with holder in foil package containing desiccants
2. ELISA Negative Control, 1 vial of buffer containing preservative and human serum with no IgG human antibodies to Actin, prediluted, 1.2mL
3. Actin IgG ELISA Low Positive, 1 vial of buffer containing preservative and human serum IgG antibodies to Actin, prediluted, 1.2mL
4. Actin IgG ELISA High Positive, 1 vial of buffer containing preservative and human serum IgG antibodies to Actin, prediluted, 1.2mL
5. HRP Sample Diluent, 1 vial – colored pink containing Tris-buffered saline, Tween 20, protein stabilizers and preservative, 50mL
6. HRP Wash Concentrate, 1 vial of 40x concentrate - colored red containing Tris-buffered saline and Tween 20, 25mL. Refer to the Methods Section for dilution instructions.
7. HRP IgG Conjugate, (goat), anti-human IgG, 1 vial – colored blue containing buffer, protein stabilizers and preservative, 10mL
8. TMB Chromogen, 1 vial containing stabilizers, 10mL
9. HRP Stop Solution, 0.344M Sulfuric Acid, 1 vial – colorless, 10mL

Materials provided
1. Actin IgG ELISA microwell plate (12-1 x 8 wells), with holder
2. 1.2mL prediluted ELISA Negative Control
3. 1.2mL prediluted Actin IgG ELISA Low Positive
4. 1.2mL prediluted Actin IgG ELISA High Positive
5. 50mL HRP Sample Diluent
6. 25mL HRP Wash Concentrate, 40x concentrate
7. 10mL HRP IgG Conjugate, (goat), anti-human IgG
8. 10mL TMB Chromogen
9. 10mL HRP Stop Solution, 0.344M Sulfuric Acid

Additional Materials Required But Not Provided
Micropipets to deliver 5, 100, 200-300 and 500µL
Disposable micropipet tips
Test tubes for patient sample dilutions, 4mL volume
Distilled or deionized water
1L container for diluted HRP Wash Concentrate
Microwell plate reader capable of measuring OD at 450nm (and 620nm for dual wavelength readings)

Specimen
This procedure should be performed with a serum specimen. Addition of azide or other preservatives to the test samples may adversely affect the results. Microbiologically contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.

Following collection, the serum should be separated from the clot. NCCLS Document H18-A2 recommends the following storage conditions for samples: 1) Store samples at room temperature no longer than 8 hours. 2) If the assay will not be completed within 8 hours, refrigerate the sample at 2-8°C. 3) If the assay will not be completed within 48 hrs, or for shipment of the sample, freeze at -20°C or lower. Frozen specimens must be mixed well after thawing and prior to testing.

Special Safety Precautions/Storage Conditions
1. Store all the kit reagents at 2-8°C. Do not freeze. Reagents are stable until the expiration date when stored and handled as directed.
2. Unused antigen coated microwell strips should be resealed securely in the foil pouch containing desiccants and stored at 2-8°C.
3. Diluted wash buffer is stable for 1 week at 2-8°C.

Procedural Notes:
Warnings
1. WARNING: This product contains a chemical (0.02% chloramphenicol) in the sample diluent, controls, and conjugate known to the State of California to cause cancer.
2. All human source material used in the preparation of controls for this product has been tested and found negative for antibody to HIV, HBsAg, and HCV by FDA cleared methods. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, the Actin IgG ELISA Low Positive, Actin IgG ELISA High Positive and ELISA Negative Control should be handled in the same manner as potentially infectious material.
3. Sodium Azide is used as a preservative. Sodium Azide is a poison and may be toxic if ingested or absorbed through the skin or eyes. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. Flush sinks, if used for reagent disposal, with large volumes of water to prevent azide build-up.
4. The HRP conjugate contains a dilute poisonous/corrosive chemical, which may be toxic if ingested in large amounts. To prevent possible chemical burns, avoid contact with skin and eyes.
5. TMB Chromogen contains an irritant, which may be harmful if inhaled, ingested or absorbed through the skin. To prevent injury, avoid inhalation, ingestion or contact with skin and eyes.
6. The HRP Stop Solution consists of a dilute sulfuric acid solution. Avoid exposure to bases, metals, or other compounds, which may react with acids. Sulfuric acid is a poison and corrosive, which may be toxic if ingested. To prevent chemical burns, avoid contact with skin and eyes.
7. Use appropriate personal protective equipment while working with the reagents provided.
8. Spilled reagents should be cleaned up immediately. Observe all federal, state and local environmental regulations when disposing of wastes.

Precautions
1. This product is for In Vitro Diagnostic Use.
2. Substitution of components other than those provided in this system may lead to inconsistent results.
3. Incomplete or inefficient washing and insufficient liquid removal from the ELISA well strips will cause poor precision and/or high background.
4. Adaptation of this assay for use with automated sample processors and other liquid handling devices, in whole or in part, may yield differences in test results from those obtained using the manual procedure. It is the responsibility of each laboratory to validate that their automated procedure yields test results within acceptable limits.
5. A variety of factors influence the assay performance. These include the starting temperature of the reagents, the ambient temperature, the accuracy and reproducibility of the pipetting technique, the thoroughness of washing and liquid removal from the wells of the ELISA strips, the photometer used to measure the results, and the length of the incubation times during the assay. Careful attention to consistency is required to obtain accurate and reproducible results.
6. Strict adherence to the protocol is recommended.
7. Incomplete resealing of the zip-lock pouch containing microwell strips and desiccants will result in antigen degradation and poor precision.
8. Unacceptably low absorbencies may be observed following two or more uses from a single bottle of HRP conjugate over a period of time. It is important to follow all recommended HRP conjugate handling procedures to prevent this occurrence.
9. Chemical contamination of the HRP conjugate can result from improper cleaning or rinsing of equipment or instruments. Residues from common laboratory chemicals such as formalin, bleach, ethanol or detergent will cause degradation of the HRP conjugate over time. Thoroughly rinse all equipment or instruments after the use of chemical cleaners/disinfectants.

Quality Control
1. The Actin IgG ELISA Low Positive, the Actin IgG ELISA High Positive and the ELISA Negative Control should be run with every batch of samples to ensure that all reagents and procedures perform properly.
2. Note that since the Actin IgG ELISA Low Positive, the Actin IgG ELISA High Positive and the ELISA Negative Control are prediluted, they do not control for procedural methods associated with dilution of specimens.
3. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations. Additional suitable control sera may be prepared by aliquoting pooled human serum specimens and storing at ≤ -20°C.
4. In order for the test results to be considered valid, all of the criteria listed below must be met. If any of these are not met, the test should be considered invalid and the assay repeated.
   a. The absorbance of the prediluted Actin IgG ELISA High Positive must be greater than the absorbance of the prediluted Actin IgG ELISA Low Positive, which must be greater than the absorbance of the prediluted ELISA Negative Control.
   b. The prediluted Actin IgG ELISA High Positive must have an absorbance greater than 1.0 while the prediluted ELISA Negative Control absorbance cannot be over 0.2.
   c. The Actin IgG ELISA Low Positive absorbance must be more than twice the ELISA Negative Control or over 0.25.
   d. The ELISA Negative Control and Actin IgG ELISA High Positive are intended to monitor for substantial reagent failure. The Actin IgG ELISA High Positive will not ensure precision at the assay cutoff.
   e. The user should refer to NCCLS Document C24-A for additional guidance on appropriate QC practices.
Procedure:
Method Before you start

1. Bring all reagents and samples to room temperature (20-26°C) and mix well.
2. Dilute the HRP Wash Concentrate 1:40 by adding the contents of the HRP Wash Concentrate bottle to 975mL of distilled or deionized water. If the entire plate will not be run within this period, a smaller quantity can be prepared by adding 2.0mL of the concentrate to 78mL of distilled or deionized water for every 16 wells that will be used. The diluted buffer is stable for 1 week at 2-8°C.
3. Prepare a 1:101 dilution of each patient sample by adding 5µL of sample to 500µL of HRP Sample Diluent. Diluted samples must be used within 8 hours of preparation. **DO NOT DILUTE** the Actin IgG ELISA Low Positive, Actin IgG ELISA High Positive and ELISA Negative Control.
4. Determination of the presence or absence of Actin using arbitrary units requires two wells for each of the three controls and one or two wells for each patient sample. It is recommended that samples be run in duplicate.

Assay Procedure

1. **ALL REAGENTS MUST BE BROUGHT TO ROOM TEMPERATURE (20-26°C) PRIOR TO BEGINNING THE ASSAY.** Place the required number of microwells/strips in the holder. Immediately return unused strips to the pouch containing desiccants and seal securely to minimize exposure to water vapor.
2. Add 100µL of the **prediluted** Actin IgG ELISA Low Positive, the Actin IgG ELISA High Positive, the ELISA Negative Control and the diluted patient samples to the wells. Cover the wells and incubate for 30 minutes at room temperature on a level surface. The incubation time begins after the last sample addition.
3. Wash step: Thoroughly aspirate the contents of each well. Add 200-300µL of the **diluted** HRP Wash buffer to all wells then aspirate. Repeat this sequence twice more for a total of three washes. Invert the plate and tap it on absorbent material to remove any residual fluid after the last wash. It is important to completely empty each well after each washing step. Maintain the same sequence for the aspiration as was used for the sample addition.
4. Add 100µL of the HRP IgG Conjugate to each well. Conjugate should be removed from the bottles using standard aseptic conditions and good laboratory techniques. Remove only the amount of conjugate from the bottle necessary for the assay. **TO AVOID POTENTIAL MICROBIAL AND/OR CHEMICAL CONTAMINATION, NEVER RETURN UNUSED CONJUGATE TO THE BOTTLE.** Incubate the wells for 30 minutes as in step 2.
5. Wash step: Repeat step 3.
6. Add 100µL of TMB Chromogen to each well and incubate in the dark for 30 minutes at room temperature.
7. Add 100µL of HRP Stop Solution to each well. Maintain the same sequence and timing of HRP Stop Solution addition as was used for the TMB Chromogen. Gently tap the plate with a finger to thoroughly mix the wells.
8. Read the absorbance (OD) of each well at 450nm within one hour of stopping the reaction. If bichromatic measurements are desired, 620nm can be used as a reference wavelength.

Reporting Results:
Interpretation of Results

The ELISA assay is very sensitive to technique and is capable of detecting even small differences in patient populations. The values shown below are suggested values only. Each laboratory should establish its own normal range based upon its own techniques, controls, equipment and patient population according to their own established procedures.

The sample can then be classified as negative, weak positive, or moderate to strong positive according to the table below.

<table>
<thead>
<tr>
<th>Units</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>&lt;20</td>
</tr>
<tr>
<td>Weak Positive</td>
<td>20 – 30</td>
</tr>
<tr>
<td>Moderate to Strong Positive</td>
<td>&gt;30</td>
</tr>
</tbody>
</table>

1. A positive result indicates the presence of Actin antibodies and suggests the possibility of autoimmune hepatitis or chronic active hepatitis.
2. A negative result indicates no Actin antibody or levels below the negative cut-off of the assay.
3. It is suggested that the results reported by the laboratory should include the statement: “The following results were obtained with the INOVA QUANTA Lite™ Actin IgG ELISA. Actin values obtained with different manufacturers’ assay methods may not be used interchangeably. The magnitude of the reported IgG levels cannot be correlated to an endpoint titer.”
Calculations

The average OD for each set of duplicates is first determined. The reactivity for each sample can then be calculated by dividing
the average OD of the sample by the average OD of the Actin IgG ELISA Low Positive. The result is multiplied by the number
of units assigned to the Actin IgG ELISA Low Positive found on the label.

\[
\text{Sample Value} = \frac{\text{Sample OD}}{\text{Actin IgG ELISA Low Positive OD}} \times \text{Actin IgG ELISA Low Positive (units)}
\]

Reactivity is related to the quantity of antibody present in a non-linear fashion. While increases and decreases in patient antibody
concentrations will be reflected in a corresponding rise or fall in reactivity, the change is not proportional (i.e. a doubling of the
antibody concentration will not double the reactivity). If a more accurate quantitation of patient antibody is required, serial
dilutions of the patient sample should be run and the last dilution to measure positive in the assay should be reported as the
patient's antibody titer.

Expected Values & Specific Performance Characteristics

The ability of the QUANTA Lite™ Actin IgG ELISA to detect actin antibodies was evaluated by comparison to a commercially
available immunofluorescent test and by evaluation of clinically defined patient samples. Results of the immunofluorescent test
were determined according to the manufacturer's direction insert.

Normal Range

The normal range study was performed in the research laboratory at INOVA Diagnostics, Inc. One hundred and fifty random
normal serum samples were selected and tested by the QUANTA Lite™ Actin IgG ELISA. This population consisted of 89
males ranging in age from 18 to 70 years (mean 31 years) and 61 females ranging in age from 17 to 74 years (mean 36 years).
Only 3 of these 150 samples tested positive. Two samples had a moderate to strong result of 75 and 31 units and the other sample
was only weakly positive at 21 units. The positive cutoff for this assay is 20 units. The average value for these 150 normal
samples was 7.3 units.

The 3 positive normal samples were tested on the immunofluorescent- based NOVA Lite™ ANA Plus Mouse Kidney & Stomach
kit. The strongly positive samples (75 and 31 units) reacted with a classic actin positive smooth muscle pattern. These samples
produced brightly fluorescing reactions with the smooth muscle of the blood vessels of the kidney, the muscularis of the stomach
as well as with the contractile protein cords running between the gastric parietal cells. The more weakly reactive sample (21
units) exhibited an atypical, more reticulin-like staining of the smooth muscle tissue.

Relative Agreement between ELISA and Immunofluorescence

To determine the relative sensitivity and specificity of the assay, 83 samples submitted for smooth muscle antibody testing from
the table above plus another 150 normal samples were tested by both the QUANTA Lite™ Actin IgG ELISA and another
commercial IFA method. Of the 233 samples, 65 were positive and 136 negative by both methods. Thirty two samples were
positive by IFA but not by the ELISA method. Of these 32 samples found IFA positive yet ELISA negative, 11 were from the
normal group and 17 of the remaining 21 samples were IFA positive but only at a 1:40 dilution.

<table>
<thead>
<tr>
<th>QUANTA Lite™ Actin IgG</th>
<th>IFA Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ 65</td>
<td>- 0</td>
</tr>
<tr>
<td>+ 32</td>
<td>136</td>
</tr>
<tr>
<td>Positive Agreement</td>
<td>Negative Agreement</td>
</tr>
<tr>
<td>67.0%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Overall Agreement 86.3%

Clinical Sensitivity and Specificity

The following is a compilation of clinical data obtained from studies conducted in the laboratories at INOVA as well as from 1
external study.

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Number</th>
<th>Number Positive</th>
<th>% Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune Hepatitis (AIH)</td>
<td>214</td>
<td>155</td>
<td>72.4</td>
</tr>
<tr>
<td>Cryptogenic Hepatitis</td>
<td>9</td>
<td>3</td>
<td>33.0</td>
</tr>
<tr>
<td>Autoimmune cholangitis</td>
<td>8</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>Primary biliary cirrhosis (PBC)</td>
<td>10</td>
<td>3</td>
<td>30.0</td>
</tr>
<tr>
<td>AIH/PBC overlap</td>
<td>9</td>
<td>7</td>
<td>77.8</td>
</tr>
<tr>
<td>AIH/PSC overlap</td>
<td>3</td>
<td>2</td>
<td>66.0</td>
</tr>
<tr>
<td>Drug induced hepatitis</td>
<td>1</td>
<td>1</td>
<td>100.0</td>
</tr>
<tr>
<td>Autoimmune hepatitis type 2</td>
<td>3</td>
<td>3</td>
<td>100.0</td>
</tr>
<tr>
<td>Viral hepatitis</td>
<td>3</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Patient Group | Number | Number Positive | % Positive
--- | --- | --- | ---
Cirrhosis | 1 | 0 | 0.0
Primary sclerosing cholangitis (PSC) | 1 | 0 | 0.0
Autoantibody positive controls | 108 | 11 | 10.0
Normals | 163 | 3 | 1.8

Sensitivity for AIH may actually be higher than indicated since many of these patients were undergoing immunosuppressive therapy prior to sample being drawn. In addition, many patients had multiple draws. Seropositivity for the above table was defined as positivity of the earliest bleed. An additional 7 AIH and 1 AIH/PBC and 1 AIH/PSC patient became positive on subsequent samples yielding sensitivities of 75.7% for the AIH group.

Cross-Reactivity
To assess potential cross-reactivity of other autoantibodies with the QUANTA Lite™ Actin IgG ELISA a total of 68 different sera were tested, each containing high levels of various commonly tested autoantibodies. Included in this group of 68 samples were 6 samples from patients with SLE, containing high levels of ANA and double stranded DNA, 2 rheumatoid factor sera, 6 sera positive for endomyosial/tissue transglutaminase, 7 sera positive for thyroid peroxidase (TPO). There were 8 ANCA positives, 4 P-ANCA and 4 C-ANCA. One glomerular basement membrane (GBM), 1 lupus anti coagulant positive and 4 each of Sm, RNP, SS-A, SS-B, Scl-70 and Jo-1 were tested. The remaining sera were 4 anticardiolipin, 3 β2 GPI, 2 prothrombin positives, 1 histone and 3 samples from type I diabetes patients that are ICA positive. Only 4 samples produced a positive result. Two samples were quite strongly positive at 83 and 66 units. When tested by IFA on the NOVA Lite™ ANA Plus Mouse Kidney & Stomach kit both samples were found to be smooth muscle antibody positive to a titer of 1:320 with a characteristic Actin pattern. Two samples were weakly positive at 26 units each. Neither of these showed any reactivity with smooth muscle tissue by immunofluorescence. Both samples were ANA/DNA positives.

Testing of 83 Known Smooth Muscle Positive Samples
The following table lists actin ELISA positivity according to smooth muscle IFA titer.

<table>
<thead>
<tr>
<th>IFA Titer</th>
<th>Number</th>
<th>Number Actin Positive</th>
<th>% Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>2560</td>
<td>1</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>1280</td>
<td>1</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>640</td>
<td>8</td>
<td>8</td>
<td>100%</td>
</tr>
<tr>
<td>320</td>
<td>7</td>
<td>6</td>
<td>86%</td>
</tr>
<tr>
<td>160</td>
<td>12</td>
<td>12</td>
<td>100%</td>
</tr>
<tr>
<td>80</td>
<td>17</td>
<td>14</td>
<td>82%</td>
</tr>
<tr>
<td>40</td>
<td>37</td>
<td>20</td>
<td>54%</td>
</tr>
<tr>
<td>Total</td>
<td>83</td>
<td>62</td>
<td>75%</td>
</tr>
</tbody>
</table>

Precision and Reproducibility
The precision and reproducibility of the assay was measured by running six replicates each of a negative (14 units), low positive (25 units) and strong positive sample (110 units) in six separate assays. Within and between run precision were calculated as follows: The standard deviation and coefficient of variation for each sample are summarized below.

<table>
<thead>
<tr>
<th></th>
<th>Negative</th>
<th>Low Positive</th>
<th>Strong Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD</td>
<td>CV</td>
<td>SD</td>
<td>CV</td>
</tr>
<tr>
<td>Overall</td>
<td>1.3</td>
<td>9.7%</td>
<td>1.4</td>
</tr>
<tr>
<td>Within Run</td>
<td>1.1</td>
<td>8.0%</td>
<td>1.4</td>
</tr>
<tr>
<td>Between Run</td>
<td>1.2</td>
<td>8.6%</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Correlation – N/A

Limitations of the Procedure
1. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.
2. Not all chronic active hepatitis or primary biliary cirrhosis patients are positive for actin antibodies.
3. Not all smooth muscle positive samples will have actin antibodies.
4. Results of this assay should be used in conjunction with clinical findings and other serological tests.
5. The assay performance characteristics have not been established for matrices other than serum.
6. At this time, the effect of therapy on anti-actin autoantibodies is unknown.
References


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