

Procedure Name

Reveal[®] G3 Rapid HIV-1 Antibody Testing Procedure.

Purpose

The Reveal[®] G3 Rapid HIV-1 Antibody Test is a single use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in human serum or plasma. The Reveal[®] G3 Rapid HIV-1 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid tests are available, this test should be used in appropriate multi-test algorithms.

RESTRICTIONS

- **Sale of the Reveal[®] G3 Rapid HIV-1 Antibody Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.**
- **The Reveal[®] G3 Rapid HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the “Subject Information Brochure” prior to specimen collection and appropriate information when test results are provided.**
- **The Reveal[®] G3 Rapid HIV-1 Antibody Test is not approved for use to screen donors of blood, plasma, cells or tissues.**

BACKGROUND

Human Immunodeficiency Virus (HIV) causes Acquired Immune Deficiency Syndrome (AIDS). Of the two types of HIV (HIV type 1 and HIV type 2), HIV-1 is far more prevalent within North America and in most regions worldwide. HIV is known to be transmitted through contact with the body fluids of an infected individual. Sexual contact, exposure to blood through contaminated syringes and needles or transfusion, or from an infected mother during the birthing process or through breastfeeding are the major modes of HIV transmission.

Infection with HIV-1 and/or HIV-2 elicits an immune response resulting in the production of corresponding anti-HIV antibodies. Antibody detection tests for HIV-1/HIV-2 antibodies provide a means to aid in the diagnosis of HIV-infected individuals^{1,2}. However, when utilizing HIV antibodies to diagnose HIV infection, corresponding clinical factors must also be considered. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. On the other hand, newborns of HIV-infected mothers may carry maternal antibodies to HIV for up to eighteen months, which may not necessarily indicate the true infection status of the newborn.

Conventional laboratory testing for antibodies to HIV utilizes enzyme immunoassays (EIAs) followed by confirmation of repeatedly reactive EIAs using supplemental tests such as the Western blot test, both of which are complex, multi-step procedures. Rapid immunoassay technology has proven to be extremely useful in the diagnosis of infection and is widely utilized as a screening tool. Although use of an EIA screening test is well-suited for batch testing, the turnaround time could be several days to a few weeks.

Additionally, the complexity and cost of EIA screen testing and the required equipment may prohibit its universal utilization in medical settings with limited resources and personnel.

Rapid, less complex HIV testing could improve the delivery of medical care and HIV prevention services with substantial time and cost savings^{3,4}. Realizing the utility of rapid tests, the World Health Organization (WHO) recommends the use of alternative testing strategies using rapid and simpler HIV tests⁵. Similar recommendations were made by the United States Centers for Disease Control and Prevention (CDC) upon determining that large numbers of patients tested for HIV using conventional methods did not return to the medical facility to obtain test results. From a public health perspective, this high non-return rate has great implications for the health and welfare of an HIV- infected individual and his/her contacts⁶. The *Reveal[®] G3 Rapid HIV-1 Antibody Test* is a rapid, flow-through diagnostic immunoassay developed to utilize the performance characteristics of a conventional diagnostic immunoassay while simplifying the testing procedure to eliminate the requirement for expensive equipment and highly trained personnel and decrease turnaround time.

BIOLOGICAL PRINCIPLES OF THE TEST

The *Reveal[®] G3 Rapid HIV-1 Antibody Test* is a manually performed, visually interpreted, rapid immunoassay. The *Reveal[®] G3 Rapid HIV-1 Antibody Test* is comprised of a single-use test cartridge containing an immunoreactive test membrane. The immunoreactive test membrane is comprised of a combination of synthetic peptides corresponding to conserved regions of HIV structural proteins coated onto a membrane matrix, which functions to capture anti-HIV-1 antibodies present in human serum or plasma when a drop of the specimen is applied. Following the application of the sample, the membrane is washed with MedMira Universal Buffer to remove any non-specifically bound antibodies. Captured anti-HIV-1 antibodies are visualized through a reaction with the MedMira InstantGold™ Cap (which contains a proprietary protein A-colloidal gold conjugate) which may be followed by an optional washing step with MedMira Universal Buffer for clarification of the test result. A Reactive test result occurs only when the protein A portion of the conjugate binds to the captured antibodies, producing a distinctive red dot in the test (T) zone and a vertical red Control Line in the control (C) zone of the test membrane upon completion of the test procedure. In contrast, a Non-Reactive test result, due to the absence of the HIV-1 antibody/antigen complex, is indicated by the presence of only the vertical red Control Line on the test membrane. If the vertical red Control Line is not present, the test result is considered invalid and testing must be repeated with a new cartridge (refer to *Interpretation/Results* section below).

The test results are to be read and interpreted **immediately** following removal of the InstantGold™ Cap and/or the optional washing step with Universal Buffer. Precision pipetting, sample manipulation or specialized equipment **are not required** to perform the *Reveal[®] G3 Rapid HIV-1 Antibody Test*.

Reagents Provided

All reagents required for the *Reveal[®] G3 Rapid HIV-1 Antibody Test* are included:

1. The MedMira Universal Buffer.
2. The MedMira HIV-1 Human Test Controls.

The MedMira Universal Buffer is ready to use and is supplied in a 30mL drop dispenser bottle (used for reconstitution of MedMira Test Controls and in other procedural steps).

Following reconstitution, the Test Controls should be stored upright in the stoppered vials at 2-8°C for up to twenty-one (21) days. Discard remaining reconstituted Test Controls not used within twenty-one (21)

days. The MedMira HIV-1 Human Test Controls should be treated as liquid infectious waste and be disposed of according to local guidelines. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121°C or by incineration.

Equipment

No specialized equipment is required when using this testing procedure. All necessary supplies, with the exception of those mentioned in the Supplies section below, are provided within the test package.

Supplies

In addition to the *Reveal*[®] G3 Rapid HIV-1 Antibody Test, the following supplies are required:

1. Disposable gloves
2. Laboratory coat
3. Biohazard waste disposal bags suitable for autoclaving
4. Permanent marking pen
5. Disinfectant (household bleach)
6. Liquid waste discard container with a freshly prepared 0.5% solution of sodium hypochlorite (10% solution of household bleach)

Specimen

A. Specimen Collection

1. The *Reveal*[®] G3 Rapid HIV-1 Antibody Test can be used to test either serum or plasma specimens. Plasma obtained using EDTA, heparin, or sodium citrate as an anticoagulant is suitable for testing.
2. Specimens may be tested immediately upon receipt or stored at 2-8°C for up to five (5) days prior to testing. Specimens should be stored at -20°C or below if storage is necessary for more than five (5) days.
3. Particulate matter can block the test membrane or cause high background colour making interpretation of results difficult. **Cloudy or viscous specimens should not be used for testing.**

B. Specimen Shipping

1. If specimens are to be shipped, dispatch by the fastest means available. Specimens should be packaged in compliance with statutory regulations governing transportation of dangerous goods.
2. Serum or plasma specimens may be shipped overnight at ambient temperature. However, if the transit time is expected to exceed 24 hours and/or the ambient temperature is >35°C, specimens should be shipped at 2-8°C.

C. Specimen Handling

1. For serum or plasma that has been previously frozen:
 - a. Thaw completely at room temperature (15-27°C) and mix thoroughly by gently tapping the bottom of the capped tube.
 - b. Centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15-27°C) at 6000 rpm for at least five (5) minutes and use only the clear supernatant for testing.
2. Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed more than twice prior to use with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test.

Special Safety Precautions

1. Handle specimens, MedMira HIV-1 Human Test Controls, and all materials contacting specimens as if capable of transmitting infectious agents. It is recommended that all specimens and test reagents be handled in accordance with biosafety level 2 practices as described in Laboratory Biosafety Guidelines, Health Canada⁷, the CDC/NIH publication on Biosafety in Microbiological and Biomedical Laboratories⁸, WHO biosafety manual⁹ or CDC Universal Precautions¹⁰.
2. Do not smoke, eat, or drink in areas where specimens or test reagents are handled. Do not pipette by mouth.
3. Wear disposable gloves, laboratory coat and eye protection throughout the test procedure. Upon completion of the test, gloves must be treated as biohazardous waste and disposed of accordingly. Wash hands thoroughly after disposing of gloves.
4. Wipe spills promptly with a 1% sodium hypochlorite solution (five-fold v/v dilution of household bleach, prepared fresh daily) or other appropriate disinfectant¹¹. Contaminated materials should be disposed of as biohazardous waste.
5. Add an equal volume of freshly prepared 5% sodium hypochlorite solution (household bleach) to liquid wastes and allow them to soak for at least 1 hour for disinfection.
6. Dispose of all test specimens and materials used in the *Reveal*[®] G3 Rapid HIV-1 Antibody Test in a biohazardous waste container. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121°C or by incineration. **Note: Do not autoclave solutions that contain bleach.**
7. Sodium azide is used as a preservative in the MedMira Universal Buffer. Sodium azide forms lead or copper azide in laboratory plumbing and may explode on percussion, such as hammering. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing sodium azide.

Quality Control

Built-in Control Features

The *Reveal*[®] G3 Rapid HIV-1 Antibody Test includes a built-in procedural and reagent Control Line that demonstrates the validity of the testing procedure and reagent function. A vertical red line under the “C” (Control Area) on the test cartridge indicates that specimen has been added to the test cartridge, and that the test reagents are functioning properly. The Control Line will appear on all valid tests, regardless of whether the test result is Reactive or Non-Reactive (see **Interpretation/Results** section below).

External Quality Control

One MedMira HIV-1 Human Test Control Package is provided with the test, and is only for use with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test. Additional packages are also available as an accessory to the test. The Test Control Package includes two controls, the MedMira Positive Test Control, and the MedMira Negative Test Control. Each test control is reconstituted as indicated procedure section below. **Using individual test cartridges run one Positive and one Negative Test Control under the following circumstances to monitor proper test performance:**

- **With each new operator prior to performing testing on patient specimens.**
- **When beginning testing with a new lot of test devices.**
- **On each new shipment of tests received.**
- **If the temperature in the storage area for the tests falls outside of the 2-30°C range.**
- **If the temperature in the testing area falls outside of the 2-30°C range.**
- **At periodic intervals as required by the user facility.**

Reconstituted test controls are stable for up to twenty-one (21) days at 2-8°C. Positive and Negative Test Controls are tested using the **Procedure** described, replacing the specimen in step 6 of the **Procedure**. The Positive Control will produce a Reactive test result indicated by both the red dot in the test zone and a vertical red Control Line upon completion of the test procedure. The expected test result using the Positive Control may be less intense than test results obtained using clinical specimens. In contrast, a Non-Reactive test result is obtained with the Negative Test Control, due to the absence of the HIV-1 antibody, and is indicated by the presence of only the vertical red Control Line on the test membrane.

It is the responsibility of each laboratory using the *Reveal*[®] G3 Rapid HIV-1 Antibody Test to establish an adequate quality assurance program to ensure the proper performance of the device under its conditions of use. Contact MedMira's Sales and Marketing Department if the Positive and/or Negative Test Controls do not produce the expected results.

Procedure

Ensure that the Subject Information Brochure is provided to the test subject prior to specimen collection.

When performing the *Reveal*® G3 Rapid HIV-1 Antibody Test it is important to adhere to the following procedural notes. Failure to do so may result in inaccurate results.

1. All solutions must be completely absorbed into the test membrane before proceeding to the next step in the procedure.
2. Do not touch, mark or label the surface of the immunoreactive test membrane.
3. Perform the *Reveal*® G3 Rapid HIV-1 Antibody Test at room temperature (15-27°C).
4. Once the assay has been started, all subsequent steps should be completed without interruption.
5. Perform the test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.
6. Read the test results immediately. Failure to do so may result in inaccurate test results.

Procedure

1	<p>Reconstitute the HIV-1 Test Controls immediately prior to performing the test procedure as specified below, or retrieve previously reconstituted Reagents and allow them to equilibrate to room temperature (15-27°C) for 30-60 minutes prior to testing.</p> <p><i>MedMira Positive and Negative Test Controls</i></p> <p>One (1) vial contains sufficient quantity to perform five (5) tests.</p> <ol style="list-style-type: none">a. Using the notched corners, tear open a <i>MedMira HIV-1 Human Test Control</i> Mylar pouch.b. Remove the vial of MedMira Negative Test Control and carefully remove the stopper.c. Hold the MedMira Universal Buffer bottle on a slight angle from vertical directly above the vial to avoid air bubbles. Add six (6) drops of MedMira Universal Buffer through the buffer bottle drop dispenser tip by gently squeezing the bottle.d. Replace the stopper tightly, and gently mix by tapping the bottom of the vial until all material has dissolved. Do not mix by inverting the vial as this will cause excess foaming.e. After mixing, the solution should be clear with a slight yellow tint. If this is not the case, contact the MedMira Sales and Marketing Department for replacement.f. Repeat steps b-e above with the MedMira Positive Test Control.g. Note the dates of reconstitution and expiration (twenty-one (21) days later) on the vials with a permanent marking pen. Store the remaining reconstituted MedMira HIV-1 Human Test Controls upright in the stoppered vials at 2-8°C for up to twenty-one (21) days.h. Discard remaining reconstituted reagents not used within twenty-one (21) days. The MedMira HIV-1 Human Test Controls should be treated as liquid infectious waste and be disposed of according to local guidelines. The recommended method of disposal is autoclaving for a minimum of 1 hour at 121°C or by incineration.
2	Allow the specimen to equilibrate to room temperature (15-27°C) for 30-60 minutes prior to testing.

3	<p>Using the notched corners, tear open the required number of Test Cartridge Mylar pouches.</p> <ol style="list-style-type: none">Ensure that a desiccant packet is present in each pouch. If the desiccant packet is not present, discard that Test Cartridge Mylar Pouch and all of its contents and open a new pouch.Inspect each test cartridge to ensure that a faint blue line is visible in the Control zone (under the C on the test cartridge). If this blue line is not visible, discard that Test Cartridge Mylar Pouch and all of its contents and open a new pouch.Inspect each InstantGold™ Cap to ensure that the green plastic casing is snapped securely around the rose-coloured filter medium. If this is not the case, discard that Test Cartridge Mylar Pouch and all of its contents and open a new pouch.
4	<p>Align the test cartridges in front of the specimens to be tested. Label test cartridges on the white plastic casing with a permanent marking pen. DO NOT LABEL OR MAKE ANY MARKS ON THE IMMUNOREACTIVE TEST MEMBRANE.</p>
5	<p>Holding the MedMira Universal Buffer bottle with the drop dispenser tip on a slight angle from vertical, apply three (3) drops of MedMira Universal Buffer (through the buffer bottle drop dispenser tip) to the center of each test cartridge to prime the immunoreactive test membrane. Allow the buffer to absorb completely.</p>
6	<p>Uncap specimen tube(s). Squeeze the bulb of the disposable pipette (provided in the Test Cartridge Mylar pouch) between the thumb and the index finger. Place the tip of the pipette into the specimen. Slowly release the pressure on the bulb to draw the specimen into the channel of the pipette. Apply one (1) drop of serum or plasma specimen to the center of the test membrane. If the specimen does not completely absorb into the test membrane within 30 seconds, centrifuge an aliquot of the specimen in a small, capped tube at room temperature (15-27°C) at 6000 rpm for at least five (5) minutes. Prime a new test cartridge as in Step 5 above. Apply one (1) drop of the clear specimen supernatant to a new test cartridge. Discard the disposable pipette in a biohazard waste container after use. Ensure that the specimen has absorbed completely into the test membrane before proceeding to the next step.</p>
7	<p>Holding the MedMira Universal Buffer bottle with the drop dispenser tip on a slight angle from vertical, apply three (3) drops of MedMira Universal Buffer (through the buffer bottle drop dispenser tip) to the center of the test membrane. Allow the buffer to absorb completely. Do not touch the buffer bottle drop dispenser tip to the test membrane.</p>
8	<p>Place the InstantGold™ Cap into the well of the test cartridge. Apply twelve (12) drops of MedMira Universal Buffer to the center of the InstantGold™ Cap. Allow the solution to absorb completely. Remove the InstantGold™ Cap.</p>
9	<p>Read results immediately as indicated in the <i>Interpretation/Results</i> section. Record the results.</p> <p>*Optional – To further clarify the test results, an additional three (3) drops of Universal Buffer may be added to the center of the test membrane following the removal the InstantGold™ cap.</p>
10	<p>After recording the test results, dispose of the test cartridges, InstantGold™ Cap, empty Test Control vials, both types of disposable pipettes and other testing materials in a</p>

	biohazard waste container.
11	Follow CDC guidelines to inform the test subject of the test result and its interpretation ¹²

Interpretation/Results

Non-Reactive

The diagram to the right is an example of a Non-Reactive test result. The presence of a vertical red Control Line under the **C** and the absence of a red dot next to the **T** on the test membrane indicate that anti-HIV-1 antibodies **were not detected**. The test result is interpreted as **NEGATIVE for HIV-1 antibodies**. A uniform, faint pinkish background may be visible on the test membrane.



Reactive

The diagrams to the right are examples of a Reactive test result. The presence of both a vertical red Control Line under the **C** and a red dot next to the **T** on the test membrane, regardless of intensity, indicate that anti-HIV-1 antibodies **have been detected** in the specimen.



Invalid

The diagrams to the right are examples of an Invalid test result. The absence of the vertical red Control Line or the presence of a broken line under the **C** indicates that there has been a problem, either with the test device or the specimen, during the **Testing Procedure**. **An Invalid test result cannot be interpreted**. If an Invalid test result is obtained, the **Testing Procedure** should be repeated using a new test cartridge and specimen.



Method Limitations

1. Sale of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
2. The *Reveal*[®] G3 Rapid HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.
3. The *Reveal*[®] G3 Rapid HIV-1 Antibody Test must be used in accordance with the package insert to ensure accurate results.
4. The FDA has approved the *Reveal*[®] G3 Rapid HIV-1 Antibody Test for serum or plasma specimens only. Use of other types of specimens may not yield accurate results.
5. Test results are to be read and interpreted **immediately** following the final washing step with Universal Buffer. A delay in reading test results may yield inaccurate results.
6. Specimens that do not pass through the membrane within thirty (30) seconds after centrifugation (see Testing Procedure, step 6) are unsuitable for testing with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test.
7. Lipemic samples or specimens contaminated with bacteria may not pass through the membrane within thirty (30) seconds, and therefore may be unsuitable for testing with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test.
8. Limited studies were conducted to determine the potential effect of interfering substances and unrelated medical conditions on the performance of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test.
9. The specificity of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test for serum specimens in low-risk populations has not been evaluated.
10. Limited studies were conducted to determine the performance of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test on fresh serum and plasma specimens.
11. A Reactive test result using the *Reveal*[®] G3 Rapid HIV-1 Antibody Test suggests the presence of anti-HIV-1 antibodies in the specimen. The *Reveal*[®] G3 Rapid HIV-1 Antibody Test is intended for use as an aid in the diagnosis of infection with HIV-1. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Results of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test should not be used in isolation, but in conjunction with the clinical status, history, and risk factors of the individual being tested.
12. The intensity of the red dot (Reactive test result) does not necessarily correlate with the antibody titre of the specimen.
13. A person who has antibodies to HIV-1 is presumed to be infected with the virus except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counselling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.
14. A Non-Reactive test result with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test indicates the absence of detectable antibodies to HIV in the specimen. However, a Non-Reactive test result does not exclude the possibility of exposure to, or infection with HIV. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. A comprehensive risk history and clinical judgement should be considered before concluding that an individual is not infected with HIV.

Warnings, Procedure notes, Handling precautions, and Storage instructions

Warnings

For *In Vitro* Diagnostic Use

1. **Read the package insert completely and carefully prior to use of the *Reveal*[®] G3 Rapid HIV-1 Antibody Test. If the directions are not followed exactly, inaccurate test results may occur.**
2. **The United States Food and Drug Administration has approved this test for use with serum or plasma specimens only. Use of this test with specimens other than those specifically approved for use with the *Reveal*[®] G3 Rapid HIV-1 Antibody Test may result in inaccurate test results.**
3. **Perform the *Reveal*[®] G3 Rapid HIV-1 Antibody Test at room temperature (15-27°C).**
4. **Perform the *Reveal*[®] G3 Rapid HIV-1 Antibody Test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.**

Procedural Notes

1. All solutions must be completely absorbed into the test membrane before proceeding to the next step in the procedure.
2. Do not touch, mark or label the surface of the immunoreactive test membrane.
3. Perform the *Reveal*[®] G3 Rapid HIV-1 Antibody Test at room temperature (15-27°C).
4. Once the assay has been started, all subsequent steps should be completed without interruption.
5. Perform the test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.
6. Read the test results immediately. Failure to do so may result in inaccurate test results.

Handling Precautions

1. Use each test cartridge, InstantGold[™] Cap, and specimen pipette only once and dispose of properly (see *Safety Precautions*). **Do not reuse these components.**
2. **Do not touch the immunoreactive test membrane.**
3. Do not use the *Reveal*[®] G3 Rapid HIV-1 Antibody Test or any of its components beyond the expiration date. The expiration date is printed on all labels. Always check the expiration date prior to testing. Reconstituted test controls are stable for up to twenty-one (21) days, stored at 2-8°C.
4. Do not interchange reagents or devices from different lots.
5. To prevent contamination, do not interchange stoppers on the vials (MedMira HIV-1 Human Test Controls).
6. Exercise care in handling test components to prevent contamination.
7. Adequate lighting is required to read the test result.

Storage Instructions

1. Unopened *Reveal*[®] G3 Rapid HIV-1 Antibody Tests should be stored in a dry area at 2-30°C.
2. Keep the test cartridges and reagents in sealed packages until use.

3. Following reconstitution, the MedMira HIV-1 Human Test Controls may be used or stored at 2-8°C for up to twenty-one (21) days. Ensure that stoppers are secure during storage.
4. If tests and reagents are stored at refrigerated temperatures, allow all test components and specimens to equilibrate to room temperature (15-27°C) for 30-60 minutes prior to opening the packages.

References

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Related Documents

Reveal[®] G3 Rapid HIV-1 Antibody Test Package Insert
Subject Information Brochure
Customer Letter

Appendixes

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Approval Signatures