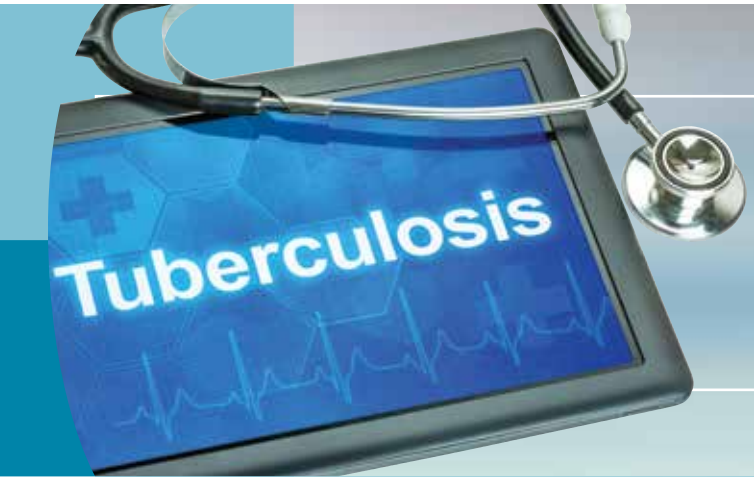


TB TESTING
FOR BIOLOGICS AND OTHER IMMUNOSUPPRESSIVE THERAPY

Common Conditions by Specialty[1]

Gastroenterology

- Moderately to severely active **Crohn's Disease**
- Moderately to severely active **Pediatric Crohn's Disease**
- Moderately to severely active **Ulcerative Colitis**
- Moderately to severely active **Pediatric Ulcerative Colitis**

Rheumatology

- Moderately to severely active **Rheumatoid Arthritis**
- Active **Psoriatic Arthritis**
- Active **Ankylosing Spondylitis**

Dermatology

- Chronic severe **Plaque Psoriasis**

Common autoimmune disorders such as inflammatory bowel disease, Crohn's disease, rheumatoid arthritis, or plaque psoriasis are commonly treated with biologics in order to slow the progression of the disease.[1] Because biologics work on the patient's immune system[2], the package insert for many biologics instructs the prescriber to perform a tuberculosis (TB) test before the patient starts on the biologic. Common biologics include infliximab[1], adalimumab[3], and certolizumab[4] (Humira[3], Enbrel[5], Otezla[6], and Xeljanz[7]) which can cause a latent tuberculosis infection (LTBI) to activate.

Approximately 11 million individuals in the US are currently infected with LTBI, thus it is critical for patients to be screened for TB infection prior to initiation of immunosuppressive treatment, including biologic agents for autoimmune diseases.[8]

QuantiFERON®-TB Gold is a recommended screening test for those patients being placed on biologic treatment and other immunosuppressive therapy.

Existing 2012 guidelines from the American College of Rheumatology[9] provide:

- TB screening for patients with rheumatoid arthritis (RA) is recommended before starting biologic agents and an IGRA (such as QuantiFERON) can be utilized in all patients being tested, and is preferred for patients who have had prior BCG vaccination.[9]
- Repeat or annual testing is only recommended for RA patients who live, travel, or work in situations where TB exposure is likely while continuing their biologic treatment.[9]

New 2016 guidelines from the American Thoracic Society/ Infectious Diseases Society of America and CDC[10] provide:

IGRAs (such as QuantiFERON) are now preferentially recommended over the skin test (TST) in persons 5 years of age or older who meet the following criteria:[10]

- are likely to be infected with *M tuberculosis* (Mtb),
- have a low or intermediate risk of disease progression,
- for whom it has been decided that testing for LTBI is warranted, and
- either have a history of BCG vaccination or are unlikely to return to have their TST read.

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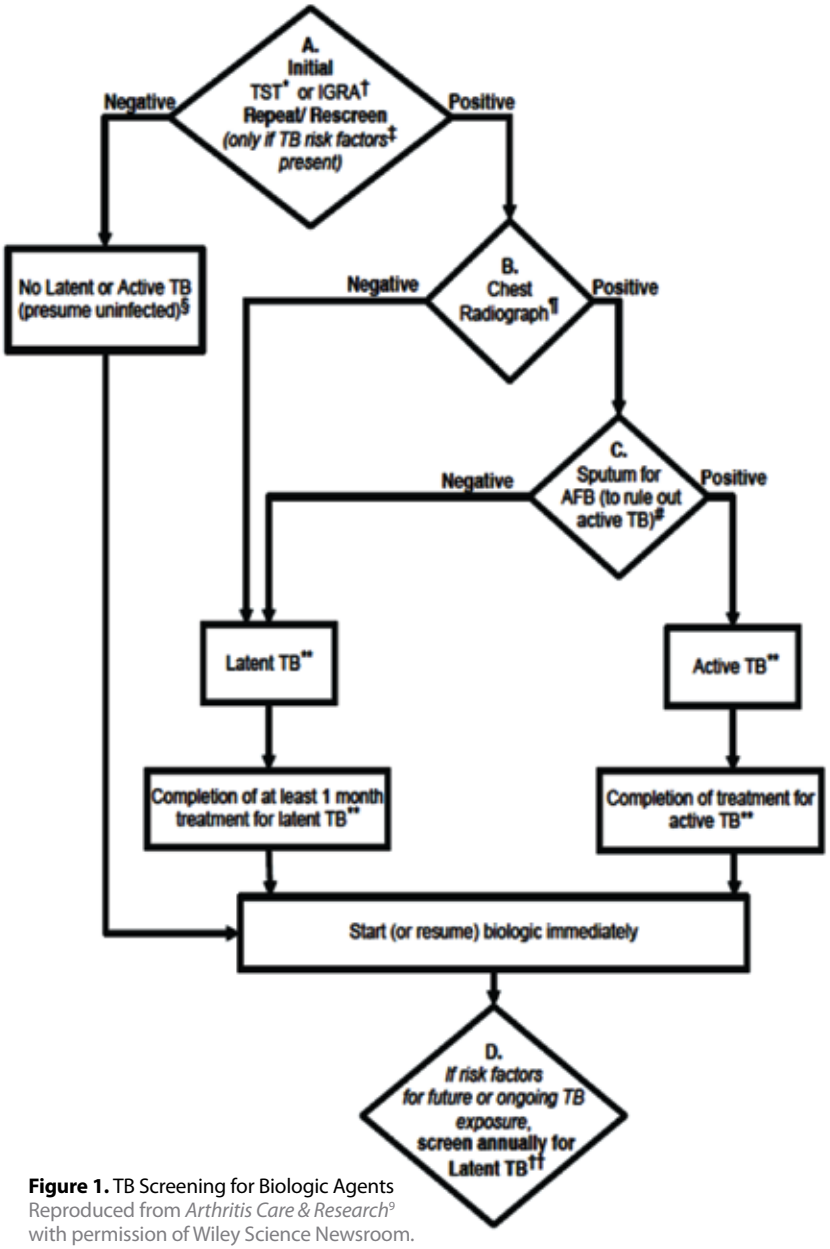


Figure 1. TB Screening for Biologic Agents
Reproduced from *Arthritis Care & Research*[9] with permission of Wiley Science Newsroom.

2012 American College of Rheumatology recommendations update for tuberculosis (TB) screening with biologic agent use. Depending on a patient's current therapy, the management may begin at an appropriate rectangle in the figure, rather than only at the top of the figure. The level of evidence supporting each recommendation for TB reactivation was "C," except for initiation of biologic agents in patients being treated for latent TB infection, where the level of evidence was "B."
* Anergy panel testing is not recommended.
† Interferon-γ-release assay (IGRA) is preferred if the patient has a history of BCG vaccination.
‡ Risk factors for TB exposure are defined based on a publication from the US Centers for Disease Control and Prevention as: close contacts of persons known or suspected to have active TB; foreign-born persons from areas that have a high incidence of active TB (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia); persons who visit areas with a high prevalence of active TB, especially if visits are frequent or prolonged; residents and employees of congregate settings whose clients are at an increased risk for active TB (e.g., correctional facilities, long-term care facilities, and homeless shelters); health care workers who serve clients who are at an increased risk for active TB; populations defined locally as having an increased incidence of latent Mycobacterium tuberculosis infection or active TB, possibly including medically underserved, low-income populations, or persons who abuse drugs or alcohol; and infants, children, and adolescents exposed to adults who are at an increased risk for latent M tuberculosis infection or active TB (14).
§ If the patient is immunosuppressed and false-negative results are more likely, consider repeating screening test(s) with tuberculin skin test (TST) or IGRA.
¶ Chest radiograph may also be considered when clinically indicated in patients with risk factors, even with a negative repeat TST or IGRA.
# Obtain respiratory (e.g., sputum, bronchoalveolar lavage fluid) or other samples as clinically appropriate for acid-fast bacilli (AFB) smear and culture and consider referral to a TB specialist for further evaluation and treatment.
** In a patient diagnosed with latent or active TB, consider referral to a specialist for the recommended treatment.
†† Patients who test positive for TST or IGRA at baseline often remain positive for these tests even after successful treatment of TB. These patients need monitoring for clinical signs and symptoms of recurrent TB disease, since repeating tests will not allow help in diagnosis of recurrent TB.

Number	Name	Use
182873	QuantiFERON®-TB Gold	The QuantiFERON®-TB Gold test is an in vitro assay to aid in the diagnosis of both latent and active infection with *Mycobacterium tuberculosis*.
183244	QuantiFERON®-TB Gold (Client Incubated)	The QuantiFERON®-TB Gold test is an in vitro assay to aid in the diagnosis of both latent and active infection with *Mycobacterium tuberculosis*.

Visit the online Test Menu at **www.LabCorp.com** for full test information, including CPT codes and specimen collection requirements.

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3. HUMIRA [package insert]. North Chicago, IL: Abbott Laboratories. 2012.
4. CIMZIA® [package insert]. Smyrna, GA: UCB, Inc. 2016.
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6. Yu DT. General guidelines for use of anti-tumor necrosis factor alpha agents in ankylosing spondylitis and in peripheral and non-radiographic axial spondyloarthritis. 2017. www.uptodate.com.
7. Xeljanz [package insert]. New York, NY: Pfizer Labs. 2012.
8. Department of Health and Human Services/Centers for Disease Control and Prevention. Updated guidelines for using Interferon gamma release assays to detect *Mycobacterium tuberculosis* infection. *Morbidity and Mortality Weekly Report*, Jun 25, 2010.
9. American College of Rheumatology. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care & Research*, May 2012; 64(5):625-639.
10. Lewinsohn DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/ Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. *Clin Infect Dis*, Jan 2017; 64(2):111-115.

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