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**Pre-Exposure Prophylaxis for Prevention of HIV infection  
Clinical guidelines****Key Principles for Prescribing PrEP**

The following information is from New York State Department of Health AIDS Institute: Guidance for the use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV transmission. [www.hivguidelines.org](http://www.hivguidelines.org).

- **PrEP should not be offered as a sole intervention** for HIV prevention. PrEP should only be prescribed **as part of a comprehensive prevention plan**.
- PrEP may **help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive**.
- PrEP is indicated for individuals who have a **documented negative HIV test result** and are at **ongoing high risk for HIV infection**. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. **Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available**.
- **Efficacy of PrEP is dependent on adherence**. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.
- Although consistent condom use is a critical part of a prevention plan, **lack of use of barrier protection is not a contraindication to PrEP**.
- PrEP is contraindicated in individuals with **documented HIV infection** or **creatinine clearance <60 mL/min**, and in **those who are not ready to adhere to daily PrEP**.
- **The first prescription of PrEP** (Truvada 1 tablet PO daily) **should only be for 30 days** to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the **patient should then return for 3-month HIV testing** and other assessments. After that visit, **prescriptions can be given for 90 days, provided that the patient is adherent**.
- Patients receiving PrEP require **regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects**. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.
- **For patients who receive a reactive HIV screening test result or for whom acute infection is suspected, initiate fully active ART**.

**Potential Candidates for PrEP**

PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given.

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Clinicians should discuss PrEP with the following non-HIV-infected individuals who have substantial and ongoing risk:

- Men who have sex with men (MSM) who engage in unprotected anal intercourse
- Individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner
- Male-to-female and female-to male transgender individuals engaging in high-risk sexual behaviors
- Individuals engaging in transactional sex, such as sex for money, drugs, or housing
- Injection drug users who report any of the following behaviors: sharing injection equipment (including to inject hormones among transgender individuals), injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors
- Individuals who use stimulant drugs associated with high-risk behaviors, such as methamphetamine
- Individuals diagnosed with at least one anogenital sexually transmitted infection in the last year
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who demonstrate continued high-risk behavior or have used multiple courses of nPEP.

**Medical Contraindications:**

- Documented HIV infection
- Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received TDF/FTC for PrEP
- Creatinine clearance <60 mL/min

Lack of readiness to adhere to a daily PrEP regimen is also a contraindication. Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level.

**Important Considerations when Prescribing PrEP**

**Does the patient have chronic active hepatitis B virus (HBV) infection?** TDF/FTC is active against HBV infection.

- Although not FDA-approved for the treatment of HBV, TDF/FTC may be used simultaneously as treatment for HBV infection and as PrEP.
- Discontinuation of TDF/FTC requires close monitoring in patients with chronic hepatitis B infection because of the concern for rebound viremia.

**Is the patient pregnant or attempting to conceive?** PrEP may be one of several options to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive.

- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy.
- After discussing the potential risks of TDF/FTC, recommend continuation of PrEP during pregnancy or breastfeeding for those with ongoing risk for HIV.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry.

**Is the patient an adolescent?**

To date, no studies have been published on the use of PrEP in individuals younger than 18 years of age, but studies in this population are underway. In addition to the use of TDF/FTC

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in HIV treatment, and PEP for adolescents 13-18 years of age, the CDC and the International Antiviral Society-USA have now extended the use of TDF/FTC to include PrEP for adolescents at high sexual or other behavioral risk for HIV infection.

- Consider PrEP for adolescents at high risk for HIV.
- Carefully weigh the potential benefits and risks, including acquiring HIV infection, before prescribing PrEP to a younger adolescent. In addition to known concerns about renal complications associated with tenofovir use, there are theoretical concerns from osteopenia, particularly in younger age groups.
- Make clear that the efficacy of PrEP is highly dependent on strict adherence.
- Refer to the institution's policy or consult with the institution's legal department about consent to care for adolescents under 18 years of age according to Florida law.

**Is the patient at risk for chronic kidney disease (>65 years of age, black race, hypertension, or diabetes)?**

- Discuss possibility of kidney disease with individuals who have pre-existing risk factors.

**Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?**

- Obtain a thorough medication history.

**Does the patient have osteopenia/osteomalacia/osteoporosis? There may be a risk of bone loss associated with tenofovir.**

- Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia.

### Pre-Prescription Laboratory Tests

#### **Baseline HIV Test**

- Obtain 4th generation (recommended) or 3rd generation (alternative) rapid HIV test
- Perform nucleic acid amplification test (NAAT, viral load) for HIV for:
  - Patients with symptoms of acute infection
  - Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month

**Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP.**

#### **Basic Metabolic Panel**

- Do not initiate PrEP in patients with creatinine clearance <60 mL/min

#### **Urinalysis**

- Proteinuria is an early warning sign of tenofovir toxicity; baseline urinalysis is necessary to identify pre-existing proteinuria

#### **Serology for Viral Hepatitis A, B, and C**

- Immunize against hepatitis A and B in non-immune patients

#### **Screening for Sexually Transmitted Infections**

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- NAAT for gonococcal and chlamydial infection — test sites of exposure (genital, rectal, pharyngeal)
- Rapid plasma reagin (RPR) for syphilis

**Pregnancy Test**

- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits

**Prescribing Recommendations**

**Prescription for PrEP should not be given until the patient is confirmed to have a negative HIV test result:**

**First Prescription:** 30-day supply with no refills

**Second Prescription given at 30-day visit:** 60-day supply with no refills

- 3-month HIV test is needed before a 90-day supply can be given

**Subsequent Prescriptions:** no more than 90-day supply, confirmed negative HIV test result required for refill

**Recommended Regimen\*:**

**Truvada 1 tablet PO daily** (Tenofovir 300 mg + Emtricitabine 200 mg)

\* PrEP with antiretroviral agents other than TDF/FTC cannot be recommended at this time

**Common Side Effects:** Headache, abdominal pain, weight loss but side effects usually resolve or improve after first month

**PrEP Follow-Up Encounters**

At each visit:	
<ul style="list-style-type: none"> <li>• Assess adherence</li> <li>• Provide risk-reduction counseling</li> <li>• Offer condoms</li> <li>• Assess/manage side effects, <i>follow-up 2 weeks after initiation to assess side effects (in person or by phone)</i></li> </ul>	
<b><u>Laboratory Testing: Follow-up and Monitoring</u></b>	
<b>Laboratory Test</b>	<b>Frequency</b>
<b>HIV Testing</b>	
<ul style="list-style-type: none"> <li>• 4<sup>th</sup> generation (recommended) or 3<sup>rd</sup> generation (alternative) HIV screening test</li> </ul>	<ul style="list-style-type: none"> <li>• Every 3 months, <i>and</i> <ul style="list-style-type: none"> <li>○ Whenever there are symptoms of acute HIV infection (HIV screening &amp; HIV RNA test)</li> </ul> </li> </ul>
<b>STI screening</b>	
<ul style="list-style-type: none"> <li>• Ask about symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• Every visit</li> </ul>

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<ul style="list-style-type: none"> <li>• NAAT to screen for gonorrhea and chlamydia, based on sites of exposure</li> <li>• Rapid plasma regain (RPR) for syphilis</li> <li>• Inspection for anogenital lesions</li> </ul>	<ul style="list-style-type: none"> <li>• At least every 6 months, even if asymptomatic (Monogamous discordant couples may not need STI screening as frequently) <i>and</i></li> <li>• Whenever symptoms are reported</li> </ul>
<b>Hepatitis C screening</b>	
<ul style="list-style-type: none"> <li>• Hepatitis C IgG</li> </ul>	<ul style="list-style-type: none"> <li>• At least annually for injection drug users, MSM and those with multiple sexual partners</li> </ul>
<b>Renal function</b>	
<ul style="list-style-type: none"> <li>• Serum creatinine and calculated creatinine clearance</li> </ul>	<ul style="list-style-type: none"> <li>• Initially, then every 6 months</li> </ul>
<ul style="list-style-type: none"> <li>• Urinalysis</li> </ul>	<ul style="list-style-type: none"> <li>• Annually</li> </ul>
<b>Pregnancy testing</b>	<ul style="list-style-type: none"> <li>• Every 3 months</li> </ul>

**Discontinuation of PrEP Regimen**

<p><b>Discontinue PrEP if patient receives a positive HIV test result and:</b></p> <ul style="list-style-type: none"> <li>➤ recommend ART in consultation with a provider with extensive experience in HIV treatment</li> <li>➤ obtain genotypic testing; adjustments may be made to the ART regimen once resistance results are available</li> </ul>
<p><i>Important Note:</i> Discontinuation of TDF/FTC in patients with chronic active hepatitis B virus can cause exacerbations of hepatitis B.</p>
<p><b>Discontinue in patients who:</b></p> <ul style="list-style-type: none"> <li>➤ develop renal disease</li> <li>➤ are non-adherent to medication or appointments after attempts to improve adherence</li> <li>➤ are using medication for purposes other than intended</li> <li>➤ reduce risk behaviors to the extent that PrEP is no longer needed</li> <li>➤ request discontinuation, with referral to risk-reduction support services and documentation of referral</li> </ul> <p><i>Note:</i> For women who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether there are ongoing risks for HIV during pregnancy.</p>

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**DOH – Okaloosa: How to Obtain Medication**

Medication Procurement and Payment Options for PrEP	
Private Insurance	<ul style="list-style-type: none"> <li>• Most private insurances cover PrEP.</li> <li>• Coverage varies based on plan. There may be deductibles and co-payments                             <ul style="list-style-type: none"> <li>○ If using Curant co-payment will be covered by “cost savings”</li> </ul> </li> </ul>
Medicaid	<ul style="list-style-type: none"> <li>• PrEP prescription costs, medical appointments and lab test covered.</li> <li>• Prior approval is required and renewed every 3 months</li> </ul>
Uninsured	<ul style="list-style-type: none"> <li>• DOH – Okaloosa serves HIV-negative persons who are residents of Florida who are uninsured or underinsured. Fees are based on sliding fee scale determined by income.                             <ul style="list-style-type: none"> <li>○ Fees include provider visits and lab testing, counseling, and supportive primary care services consistent with clinical guidelines of PreP.</li> </ul> </li> <li>• Medication assistance programs (MAP) will be used for medication procurement.</li> </ul>
Medication Assistance Programs	
Gilead Co-Pay Coupon Card	<ul style="list-style-type: none"> <li>• Gilead Co-Pay Coupon Card <a href="http://www.gileadcopay.com">www.gileadcopay.com</a> <ul style="list-style-type: none"> <li>○ Covers up to \$300/month in prescription co-payments</li> <li>○ Patient must have insurance.</li> <li>○ Patient must NOT be enrolled in Medicare or Medicaid</li> <li>○ No income eligibility requirement</li> </ul> </li> </ul>
Gilead Medication Assistance Program	<ul style="list-style-type: none"> <li>• Gilead Medication Assistance Program (855) 330-5479 <a href="http://start.truvada.com/individual">http://start.truvada.com/individual</a> <ul style="list-style-type: none"> <li>○ Covers prescription costs.</li> <li>○ Patient must be uninsured or their insurance does not cover any prescription cost.</li> <li>○ Patient must have annual income less than 500% FPL.</li> </ul> </li> </ul>
Patient Access Network (PAN Grant)	<ul style="list-style-type: none"> <li>• Patient Access Network (866) 316-7263                             <ul style="list-style-type: none"> <li>○ Offers help to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays.</li> <li>○ One-time grant to cover up to \$4000 of prescription costs for one year.</li> <li>○ Patient must have private insurance, Medicare, or Medicaid.</li> <li>○ Patient must have annual income less than 500% FPL. If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.</li> </ul> </li> </ul>

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**Pre-Exposure Prophylaxis for Prevention of HIV infection  
Clinical Standard Operating Procedure**

**Client initial PrEP appointment (established or new) self-pay or No Insurance:** Use 03A1 for all visits

**1<sup>st</sup> clinical visit w/ RN**

- Schedule client with Ryan White RN. (In HMS scheduling module use: Program Component - HIV/AIDS services, Appointment Reason - Nurse –Other; schedule in walk-in clinic.)
- HMS EHR
  - Complete medical and sexual history in HMS.
  - Open clinical visit
  - Complete RFV “PrEP”, chief complaint “desired PrEP”.
  - Vital signs
  - A&P - Diagnosis (V69.2 use Provider name)
  - Document in progress note using PrEP nurse visit documentation template.
- Nurse will determine if client is a potential candidate for PrEP and should proceed with laboratory testing. If eligible, the nurse will order initial labs via PrEP standing order.
- Initial labs
  - HIV 4<sup>th</sup> generation, RPR, GC/CT (urine) (03A1 program State Lab)
  - Hepatitis Panel (09LP program State Lab if funding is available or Quest #6462 03A1)
  - GC/CT (urine) testing as applicable, including oral & rectal (03A1 State Lab)
  - Urinalysis (Test #5463 Quest 03A1)
  - Serum creatinine (Test # 375 Quest - 03A1)
  - Pregnancy test (if applicable- In house test)
- Give client Gilead MAP application and instruct to complete application. Client is responsible for completing application.
- Give client ‘Truvada Medication guide for Patients.
- Counsel on topics contained in nurse PrEP visit documentation template. **Document in progress note as above.**

**RN Review:**

- Review lab results from 1<sup>st</sup> visit to ensure all test are back and that client should proceed with process. If an abnormal test result is received, consult with provider to determine next steps.

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- If all lab results are WNL, schedule follow-up appointment with provider. Remind client to bring completed Gilead application for provider signature. Appointment should be scheduled in RW or PrEP template slots.
  - Document findings in HMS EHR.

**2<sup>nd</sup> clinical visit w/ Provider**

- HMS EHR
  - **Nurse**
    - Open clinical visit
    - Complete RFV “PrEP”, chief complaint “desired PrEP”.
    - Vital signs
  - **Provider**
    - Review medical and sexual history in HMS.
    - Complete HPI
    - Physical Exam
    - A&P using PrEP Provider documentation template.
- Review lab results to determine if client is a candidate to take PrEP.
- Use Cockcroft-Gault formula to determine creatinine clearance.
  - $$eCrCl = \frac{(140 - \text{Age}) \times \text{wt. (kg)}}{72 \times Cr} \times .85 \text{ if female}$$
- If client isn't immune to Hepatitis A & B, administer vaccination during this visit using the 09 program vaccine.
- Review side effects and signs and symptoms requiring urgent medical evaluation.
- Give client medication fact sheet listing dosing instructions and side effects.
- Counsel on consistent use of medication and condoms.
- Review and sign agreement form for initiating Truvada.
- Have client sign agreement form.
- **Document as above using HIV PrEP Provider template on J drive**
- Sign completed Gilead application, give copy of negative HIV result and print Rx for client. (Client to mail/fax application to Gilead along with copy of negative HIV result.)

Once Truvada medication is received by CHD contact client to complete HIV test # 91431 (HIV 1/2 Antigen/antibody 4<sup>th</sup> generation w/reflex) PSC from Quest. Determine when client will go to Quest and schedule appointment with nurse for medication pick-up two – three days after the additional HIV test, but not greater than 7 days.

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SOP 103-23-16**1st visit w/Nurse for Medication pick-up**

- Review HIV result. Notify provider if positive!
- Review agreement form for initiating Truvada to ensure everything is completed.
- Give medication Truvada #30 and condoms to client.
- **Document in progress note using applicable sections of HIV PrEP template on J drive.**

**2<sup>nd</sup> & 3rd visit (monthly) w/Nurse for Medication pick-up**

- Assess adherence, tolerance and commitment.
- Provide counseling and follow-up.
- **Document in progress note using applicable sections of HIV PrEP template on J drive.**

**Client initial PrEP appointment (established or new) Insured:** Use 03A1 for visit and labs

**1<sup>st</sup> clinical visit w/ RN**

- Schedule client with Ryan White RN. (In HMS scheduling module use: Program Component - HIV/AIDS services, Appointment Reason - Nurse –Other; schedule in walk-in clinic.)
- HMS EHR
  - Complete medical and sexual history in HMS.
  - Open clinical visit
  - Complete RFV “PrEP”, chief complaint “desires PrEP”.
  - Vital signs
  - A&P - Diagnosis (V69.2 use Provider name)
  - Document in progress note using PrEP nurse visit documentation template.
- Nurse will determine if client is a potential candidate for PrEP and should proceed with laboratory testing. If eligible the nurse will order initial labs via PrEP standing order from Quest as PSC (except GC/CT) and third party bill.
  - HIV 4<sup>th</sup> generation (Test # 91431)
  - Hepatitis Panel (Test #6462)
  - GC/CT (Test #11363) urine; rectal/oral swabs will need to be collected and sent as standard order
  - Urinalysis (Test #5463)
  - RPR (Test #36126)
  - Serum Creatinine (Test # 375) all 03A1
  - Pregnancy test (if applicable – In house)
- Give client ‘Truvada Medication guide for Patients’

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- Counsel on topics contained in nurse PrEP visit documentation template. **Document in progress note as above.**
  - Determine when client will have lab testing completed and schedule follow-up appointment with provider for 2 – 3 days later, but no greater than 7 days.

**RN Review:**

- Review lab results from 1<sup>st</sup> visit to ensure all test are back and that client should proceed with process. If an abnormal test result is received, consult with provider to determine next steps.
- If all lab results are WNL, continue with process.

**2<sup>nd</sup> clinical visit w/ Provider** (Appointment should be scheduled in RW or PrEP template slots)

- HMS EHR
  - **Nurse**
    - Open clinical visit
    - Complete RFV “PrEP”, chief complaint “desired PrEP”.
    - Vital signs
  - **Provider**
    - Review medical and sexual history in HMS.
    - Complete HPI
    - Physical Exam
    - A&P using PrEP Provider documentation template.
- Review lab results to determine if client is a candidate to take PrEP.
- Use Cockcroft-Gault formula to determine creatinine clearance.
  - $eCrCl = \frac{(140 - \text{Age}) \times \text{wt. (kg)}}{72 \times Cr} \times .85$  if female
- If client isn't immune to Hepatitis A & B, administer vaccination during this visit using the 09 program vaccine.
- Review side effects and signs and symptoms requiring urgent medical evaluation.
- Give client medication fact sheet listing dosing instructions and side effects.
- Counsel on consistent use of medication and condoms.
- Review and sign agreement form for initiating Truvada.
- Have client sign agreement form.
- **Document as above using HIV PrEP Provider template on J drive**
- Rx for Truvada #30 electronically to preferred pharmacy if HIV test was completed and negative within the past week. Subsequent Rx for # 60 Truvada may be given (electronically) once adherence, tolerance and commitment are assessed after 30 days of medication.

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**RN Review:**

- Client should follow-up with nurse for subsequent Rx of #60 Truvada.
- Assess adherence, tolerance and compliance with medication regime. Document in record.
- If appropriate, place additional Rx #60 Truvada on hold for provider in Emdeon and notify provider of client's tolerance etc.

**Client Follow-up at least every 90 days after initiating PrEP for ALL clients:** Use 03A1 for visit and labs

**Provider Visit every 3 months (use appropriate laboratory testing depending on insured/uninsured status).**

- Complete PSC order for HIV 4<sup>th</sup> generation (91431) and serum creatinine (375) 15 – 20 days before they run out of medication (or when they only have a two week supply of medication left).
- Schedule client follow-up appointment 3 - 5 days from lab draw date.
- Provider will review labs and document.
- Assess side effects, adherence, risk behaviors and commitment.
- Provide risk-reduction strategies and consistent and correct use of condoms.
- Assess for STI symptoms, test & treat as applicable (test at 6 months regardless of symptoms).
- Creatinine clearance every 6 months after initiation of therapy.
- Assess for pregnancy (In-house test) if applicable.
- Have provider complete Gilead refill authorization for MAP clients or send electronic Rx for insured clients.
- Give client condoms.
- Client will need to return in 90 days for follow-up.

**NOTE: Gilead requires re-enrollment and negative HIV test result every 6 months for medication assistance.**

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**Common PrEP related codes:**

ICD-9 Codes

V01.79 – Contact with or exposure to viral disease

V69.2 – High risk sexual behavior

ICD-10 Codes

Z72.5 High-risk sexual behavior

Z72.51 High Risk heterosexual behavior

Z72.52 High Risk homosexual behavior

Z72.53 High Risk bisexual behavior

Z20.82 Contact with and (suspected) exposure to other viral communicable diseases

**SNOMED**

102947004 - High Risk Sexual Behavior (finding)

288301000119101 - High Risk Heterosexual Behavior (finding)

288311000119103 High Risk Homosexual Behavior (finding)

288291000119102 - High Risk Bisexual Behavior (finding)

444107005 - Exposure to Communicable Disease (event)

CPT Description

99401 Preventive counseling (15 minutes)

99402 Preventive counseling (30 minutes)

99403 Preventive counseling (45 minutes)

99404 Preventive counseling (60 minutes)

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**Pre-Exposure Prophylaxis for Prevention of HIV infection  
Standing Order for laboratory testing**

The following may be ordered by any Registered Nurse.

Uninsured/Self-pay:

- HIV 4<sup>th</sup> generation (03A1 program State Lab)
- Hepatitis Panel (09LP program State Lab if funding is available or Quest #6462 03A1)
- GC/CT (urine) testing as applicable, including oral & rectal (03A1 State Lab)
- Urinalysis (Test #7048 Quest 03A1)
- RPR (03A1 State Lab)
- Serum creatinine (Test # 375 Quest - 03A1)
- Pregnancy test (if applicable- In house test)

Insured: Quest as PSC and third party bill (test # listed below)

- HIV 4<sup>th</sup> generation (91431)
- Hepatitis Panel (6462)
- GC/CT (11363) urine; rectal/oral swabs will need to be collected and sent as standard order
- Urinalysis (Test #7048 Quest 03A1)
- RPR (36126)
- Serum Creatinine (375) all 03A1
- Pregnancy test (if applicable – In house)

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Sally Cooper, DO  
Medical Director

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Date

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Registered Nurse Acknowledgements:

\_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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