Breakthrough T1D™
Formerly JDRF

Early Detection Assets

For Clinical Implementation of Type 1 Diabetes Screening

Resources for the early detection of type 1 diabetes (T1D) have been developed and shared by clinics actively performing T1D screening, follow-up, and monitoring. These materials can be used as reference to develop a new workflow or modify an existing workflow for early detection of T1D in various clinical settings. Clinic names have been removed.

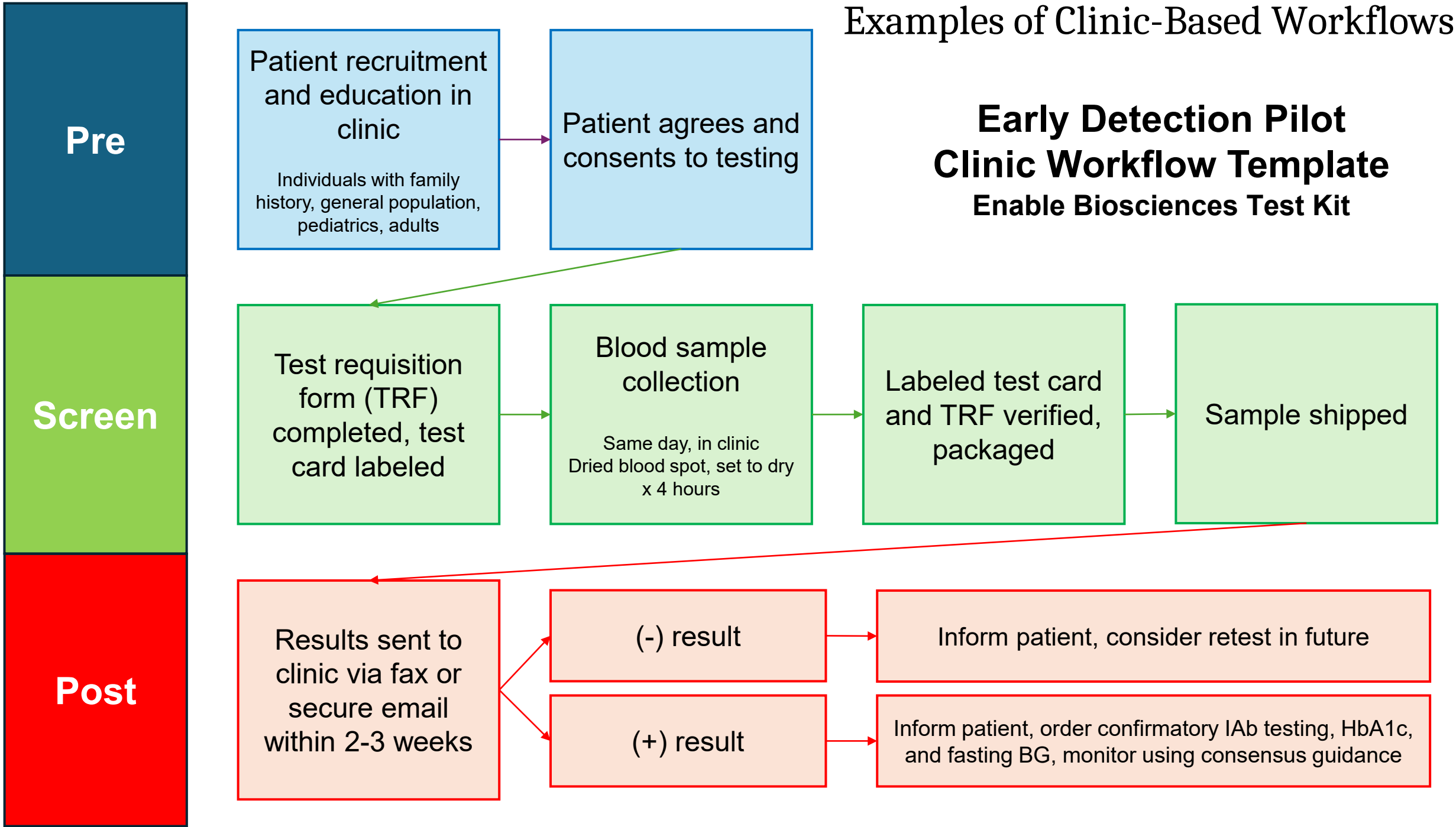
If you have questions or would like to contribute to this collection of resources, please contact EarlyDetection@BreakthroughT1D.org.

Contents

Examples of Clinic-Based Workflows

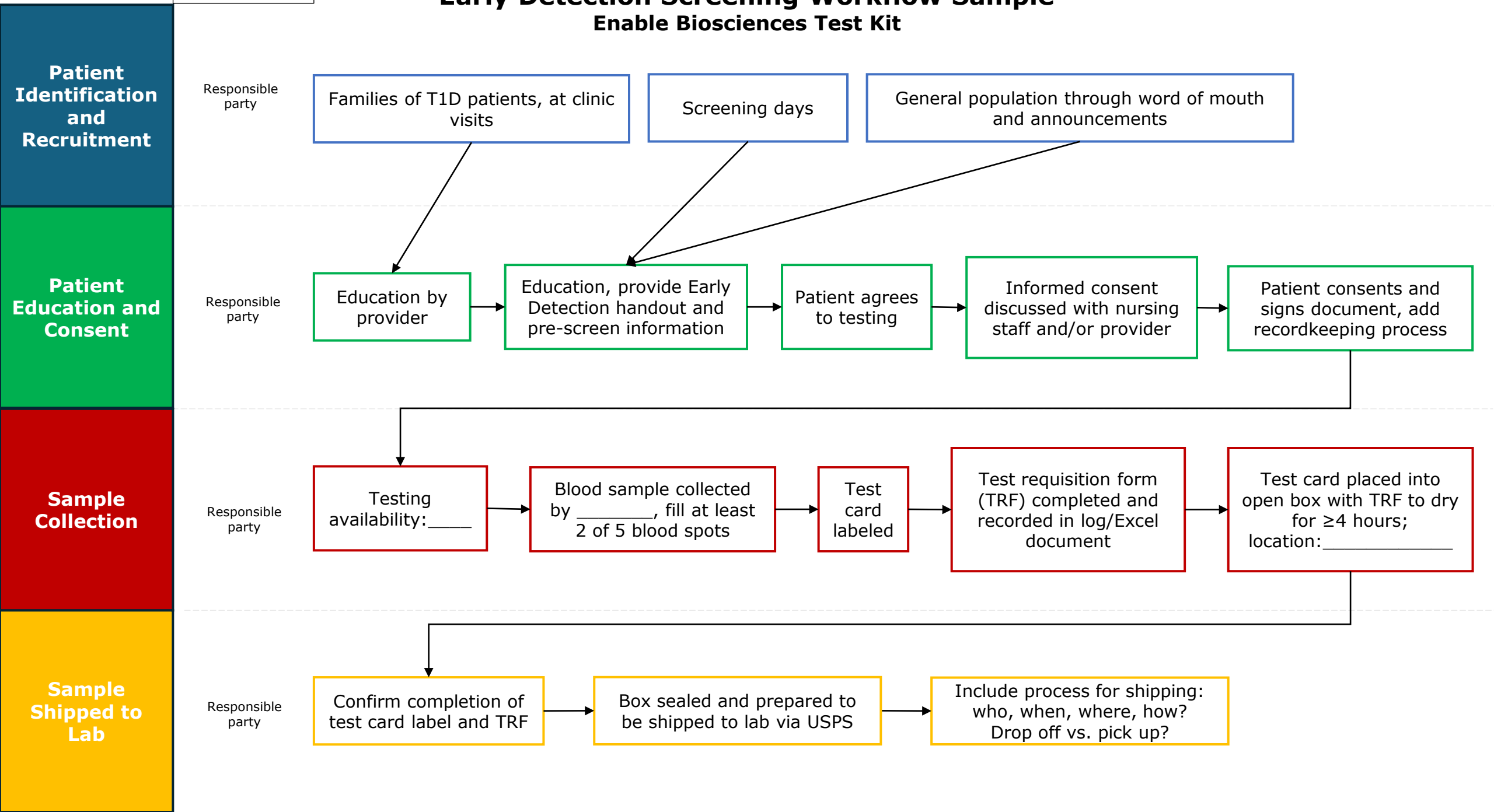
Early Detection Pilot Clinic Workflow Template

Enable Biosciences Test Kit

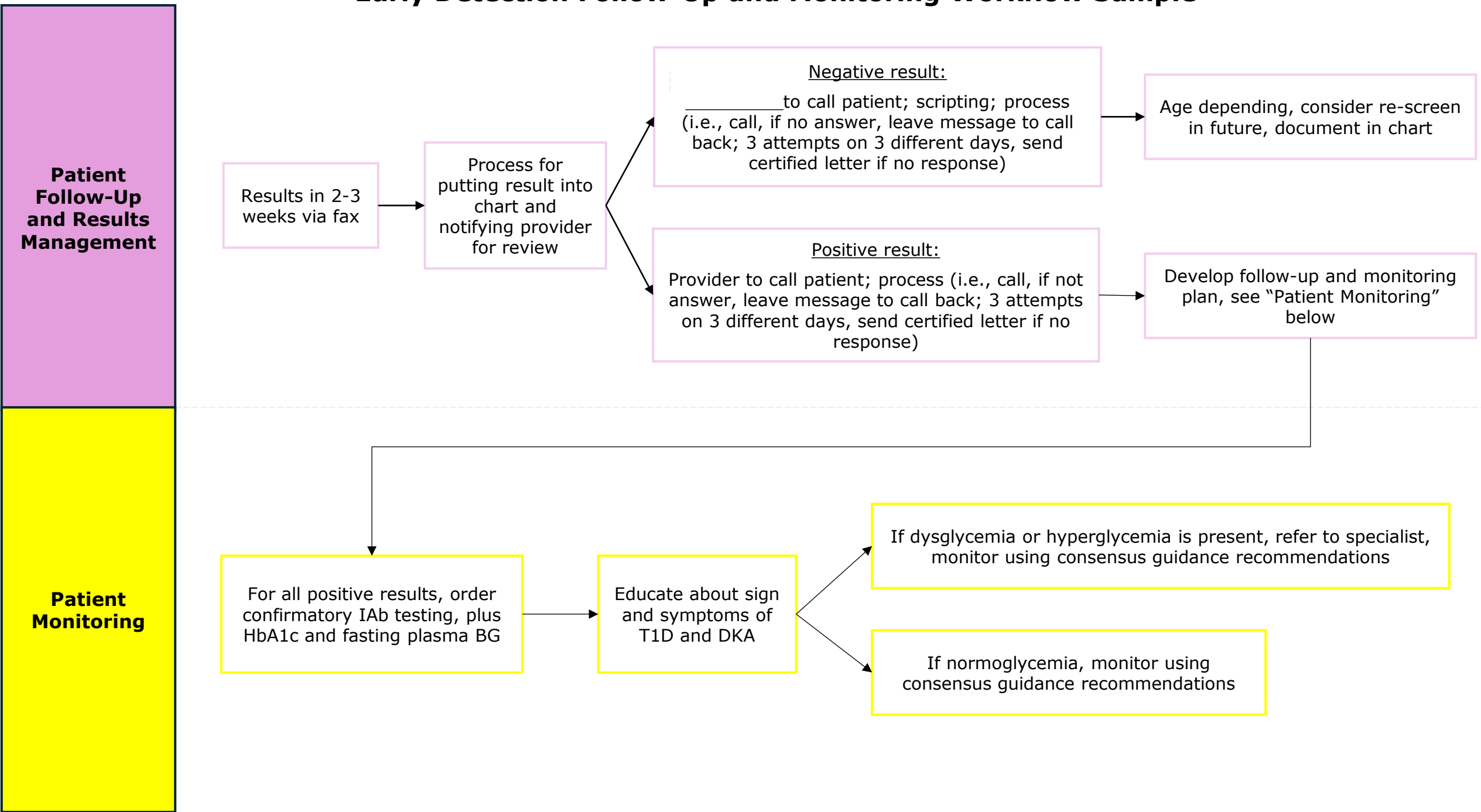


Early Detection Screening Workflow Sample

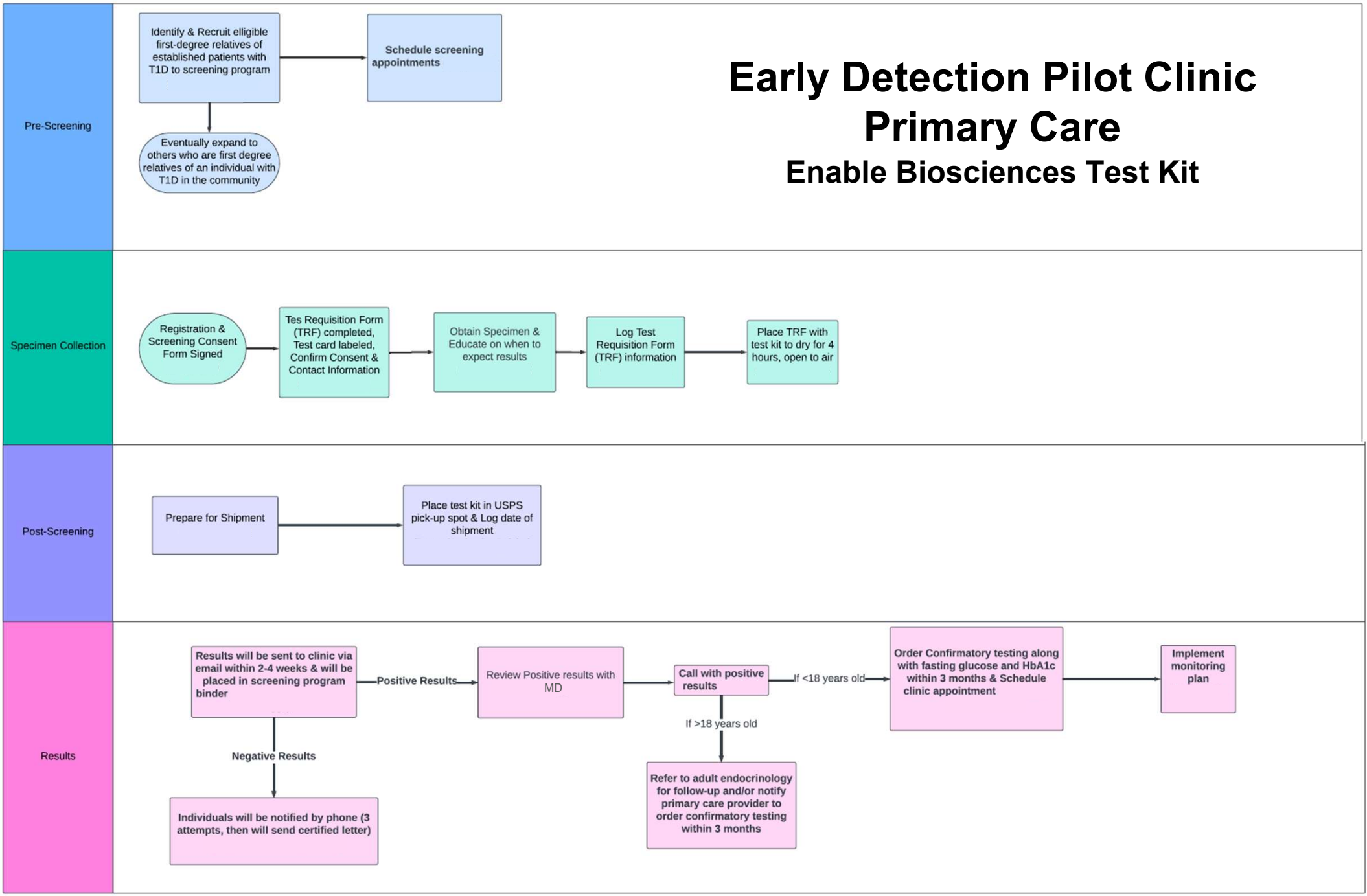
Enable Biosciences Test Kit



Early Detection Follow-Up and Monitoring Workflow Sample

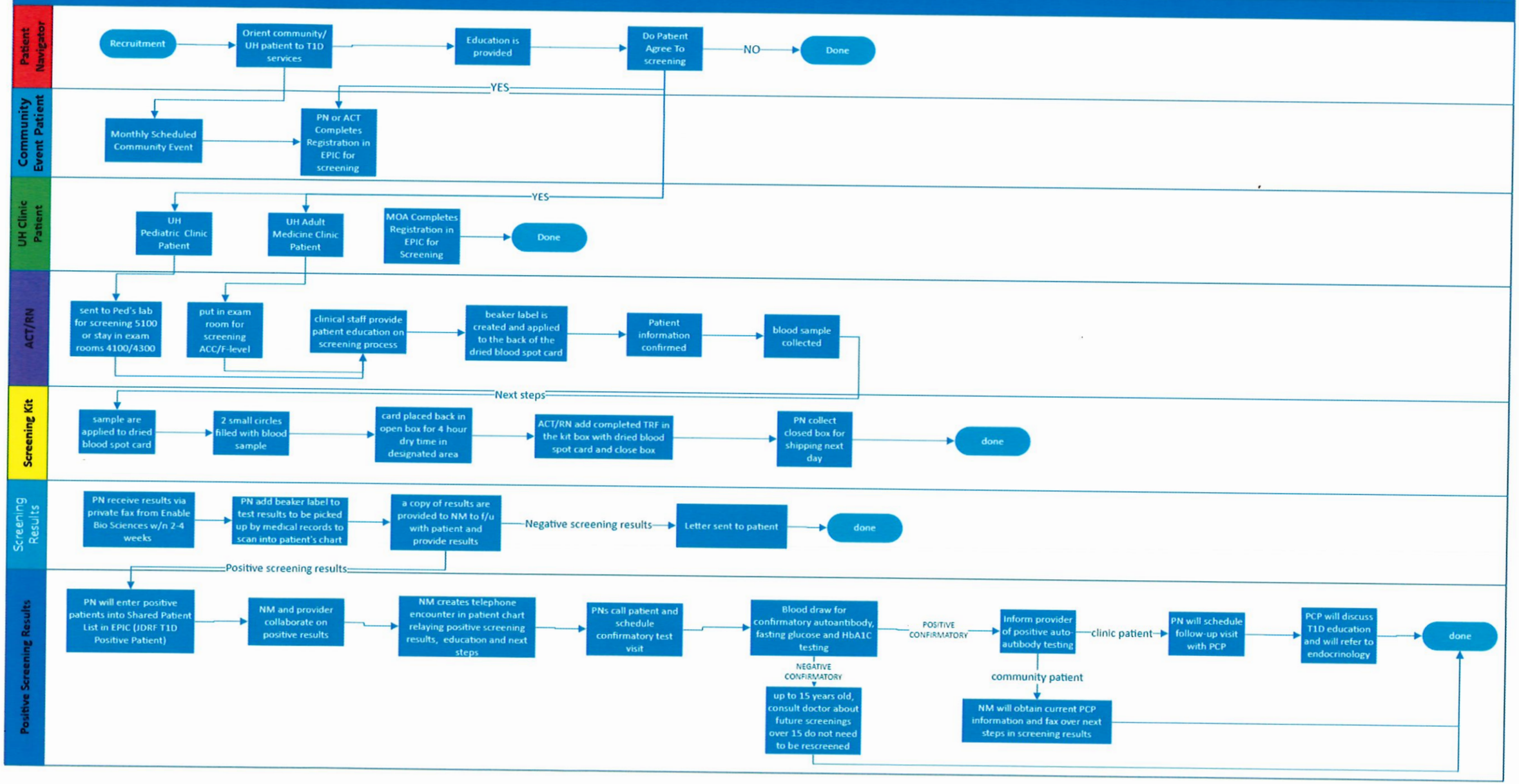


Early Detection Pilot Clinic
Primary Care
Enable Biosciences Test Kit



Type 1 Diabetes Testing Workflow

creation date: 01/09/2024
version: 3
byg/db/ch



Early Detection Workflow
Peds Endo
Enable Biosciences test kit

Pre

Patient recruitment and education in clinic

Individuals with family history of T1D or general pediatric referrals for patients with autoimmunity

Patient or guardian agrees and consents to testing

Screen

1) Patient is registered in EMR under screening so we can track
2) Test requisition form (TRF) completed; test card labeled

Blood sample collection

Same day, in clinic
Dried blood spot x 2-5 circles, set to dry x 4 hours in utility room marked area

Labeled test card and TRF verified, packaged

Sample shipped by admin lead

Post

Results sent to clinic via fax within 2-3 weeks

(-) result

Inform patient by letter and call, retest in 1-3 years and will have tickler in EMR to track

(+) result

Inform patient by letter and call,
order confirmatory testing with venous draw, HbA1c and fasting BG if 2 Ab +, monitor for dysglycemia using consensus guidance, educate regarding signs and symptoms of diabetes and DKA
And inform **primary care provider**

EPIC Smart Phrase for Positive Screening Result

.TYPE1

Patient screened positive for antibody(ies)

IA2 {YES/NO:63}

GAD {YES/NO:63}

IAA {YES/NO:63}

At Clinic Visit: {YES/NO:63}

Community Event: {YES/NO:63}

Parent informed of screening results and educated on signs and symptoms of T1D.

Polyuria (bedwetting in toilet trained children) {YES/NO:63}

Polydipsia {YES/NO:63}

Dry mouth {YES/NO:63}

Fatigue {YES/NO:63}

Increased appetite {YES/NO:63}

Unexplained Weight loss {YES/NO:63}

Blurred vision {YES/NO:63}

Family History of T1D {YES/NO:63}

Informed of next steps which includes confirmatory testing and to monitor for s/s and notify provider if any symptom develops.

Scheduled for confirmatory testing {YES/NO:63}

Date of confirmatory testing:

Sample Consent Form Used in Breakthrough T1D Early Detection Pilot Program

DISCLOSURE: Consent language will vary significantly by clinic/setting. Please work with your clinic leadership/administration to develop a consent form that is best for your setting.

ADD Clinic logo or address block

T1D Early Detection Patient Information/Consent Form

Please complete the following information: Date: _____

Patient Name_____ DOB_____ Age_____

Patient Physical Address_____
(Street Name, City, State, Zip Code)

Mailing Address (if different_____
(Street Name, City, State, Zip Code)

E-Mail Address_____

Patient Phone Number (Home)_____ (Cell)_____

Relationship of person filling out this form to person being screened: _____

Race/Ethnicity of person being screened:
❑Asian/Asian Islander ❑Black/African American ❑Hispanic/Latino ❑Multinational/Biracial
❑Native American ❑White/Caucasian ❑ Race/Ethnicity not listed here ❑Prefer not to say

Gender Identity of person being screened:
❑Male ❑Female ❑ Non-Binary ❑ Other ❑Chose not to disclose

Has the person being screened ever been diagnosed with Type 1 Diabetes:
❑Yes ❑No ❑I don't know

Does the person being screened have family member(s) with Type 1 Diabetes:
❑No ❑Yes, parent ❑Yes, sibling ❑Yes, child ❑Yes, cousin, aunt/uncle, grandparent, other ❑ I don't know

Has the person being screened ever been screened for Type 1 Diabetes previously:
❑Yes ❑No ❑I don't know

Has the person being screened ever been diagnosed with Type 2 Diabetes:
❑Yes ❑No ❑I don't know

Does the person being screened have family member(s) with Type 2 Diabetes:
❑Yes ❑No ❑I don't know

How did you hear about this test:
❑ Doctor or care team ❑Family Member ❑ Friend ❑ Online ❑ Breakthrough T1D ❑Other_____

What is your household income:
❑$0-$16,500 ❑$16,501-$63,100 ❑$63,100-$100,500 ❑$100,501-$191,950
❑$191,950-$243,700 ❑$243,700-$609,350 ❑$609,350 or more ❑Prefer not to answer

Add Clinic Address and Contact Information Here

Sample Consent Form Used in Breakthrough T1D Early Detection Pilot Program

DISCLOSURE: Consent language will vary significantly by clinic/setting. Please work with your clinic leadership/administration to develop a consent form that is best for your setting.

T1D Early Detection Patient Information/Consent Form

Please carefully read the following Informed Consent:

a) I give my consent for a member of [Clinic Name] to conduct the blood collection process on my behalf so that I, or my child, may participate in the T1D Early Detection program.
b) I authorize [Clinic Name] to disclose test results to the primary care provider:

   a. Provider Name: _____

   b. Provider Phone Number: _____

   c. Provider Fax Number:_____

   d. Provider Mailing Address: _____

   _____

c) I consent to being contacted by [Clinic Name] to discuss test results and follow-up plan of care.
d) I understand that none of my or my child's personal health information will be disclosed to Breakthrough T1D, and only the necessary personal health information will be disclosed to the testing laboratory.
e) I authorize [Clinic Name] to disclose anonymous demographic and screening information to Breakthrough T1D.
f) I understand that as part of this T1D Early Detection Program, I will not be charged for the blood collection process.
g) I understand that, as with any medical test, there is the potential for a false positive or false negative result, and that I have the right to discuss my results with the healthcare provider regarding a plan of care.

I give my consent and have been informed by [Clinic Name] about the test purpose, procedures, possible benefits, and possible risks, and I have received a copy of this Informed Consent. I have been given the opportunity to ask questions, and I have been told that I can ask additional questions at any time. I voluntarily agree to participate in the T1D Early Detection screening process.

_____ _____
First Name Last Name

_____ _____
Signature Date

_____ _____
Relationship to Patient Staff Witness

Copy of Informed Consent given to patient ☐

Add Clinic Address and Contact Information Here