Fort Worth Diagnostics

FWDX BioBlade
Vision and Scope

Version 2.0

Revision History

Date	Version	Description	Author
23/09/24	1.0	First draft of Vision and Scope	All Members
19/01/25	2.0	Changed version number to 2.0. Updated doc with suggestions made by Dr. Wei.	Nicholas Tullbane

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Vision

1. Introduction

This document defines the goals, purposes, and limitations of the software project named “Fort Worth Diagnostics BioBlade” in an effort to create a shared understanding of this software for all stakeholders. This document will explain the business domain of Fort Worth Diagnostics (FWDX) as well as the broader business context that necessitates the BioBlade tool.

1.1 Background

Fort Worth Diagnostics (FWDX) is a medical company based in Fort Worth, Texas with less than 10 employees. Their mission is to deliver “high quality reagents in a timely manner”; they are a customer focused business, “committed to bringing content to the Digital PCR and Quantitative PCR market”.

More concretely, the company creates testing kits, known as *products*, to test the presence of *pathogens* (also referred to as *targets)* in humans. In this domain, pathogen refers to any disease causing agent. A product, for example, could be a COVID or Influenza test.

FWDX competes in a domain where the largest differentiating factor between companies is the part of the assay called the *reagent*. Broadly, a reagent describes a substance used in a reaction, and it is composed of short, unique sequences of DNA called *oligos.* These strands of DNA are the components of the product that ensure the validity of the test’s result. However, as time passes, it is common for pathogens (or targets) to mutate in such a way that these reagents can no longer correctly identify the pathogens they were designed for. This poses a challenge for FWDX. They cannot sell expired products.

Thankfully, there are several government-sponsored databases (such as NCBI and GISAID) available to scientists researching pathogens. These databases are updated as pathogen mutations are found. Therefore, FWDX can compare their existing oligos against targets found in these databases to ensure the reagents still function within their margin of error. Currently, this process is both expensive and laborious - see 1.2 Current Process Flow.

1.2 Current Process Flow

To ensure an oligo is still valid, it must be checked against the most recent pathogen data in public databases. This check is manually fulfilled by a bioinformatician - who is usually a consultant from outside the company - with access to both the databases and the proprietary oligo DNA sequence. The process is outlined in the diagram below, and it starts with a company employee (labeled “Technician”) who authorizes the generation of a report:

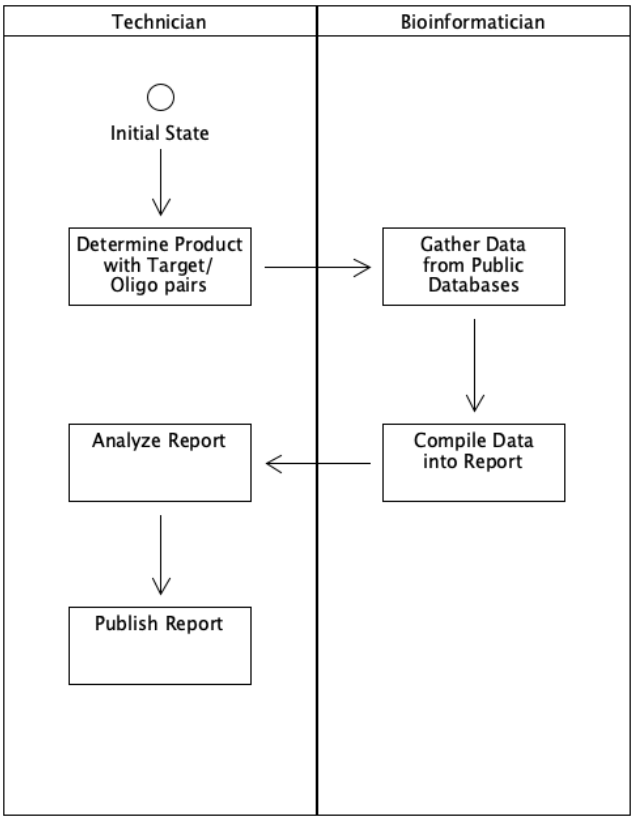

Figure (1) Current Process Flow

For the bioinformatician, gathering and compiling data from the public databases is a laborious and tedious exercise. FWDX sells products using hundreds of different oligo combinations for a large variety of targets, so this process flow can be prohibitively expensive and too slow to represent real time validity coverage for FWDX's suite of products.

1.3 References

Background 1.1: Fort Worth Diagnostics website, "About Us" section

2. Business Requirements

2.1 Business Opportunity/Problem Statement

The problem of	The manual and inefficient method of comparing submitted genetic sequences to public databases with FWDX current reagents
affects	FWDX
the impact of which is	Slow manufacturing of accurate assays when mutations occur
a successful solution would be	An automated streamlined process that allows FWDX to only check what the software provides. The process of querying the repositories and comparing genetic sequences is done strictly by software.

2.2 Business Objectives

BO-1: Enhance the genetic sequence testing process through automation to achieve 100% accuracy

Scale: Accuracy of genetic sequence testing.
Meter: Percentage of test conforming to accuracy standards
Past: Current accuracy rate (unknown)
Goal: Achieve 100% accuracy in genetic testing results
Stretch: Maintain 100% accuracy consistently over successive quarters.

BO-2: Generate and dispense comprehensive weekly reports to end users.

Scale: Consistency and coverage of report generation
Meter: Number of reports generated on time with complete data.
Past: Baseline of current reporting frequency and data completeness (unknown)
Goal: Ensure 100% of the reports are generated on time 100% data completeness
Stretch: Automate data compilation for reports to reduce preparation time by 50%

2.3 Success Metrics

SM-1: Reduction in assay turnaround time by 50% within the first year of implementation.
SM-2: Automated system to compare reagents to sequences of different organisms.

2.4 Vision Statement

For	FWDX
Who	Require dependable and swift genetic analysis
The (product name)	Is a FWDX BioBlade web application
That	Is a sophisticated solution that automates sequence comparisons to ensure accuracy and efficiency
Unlike	Manually analyzing sequences and the use of a consultant when wanting an in-depth analysis of sequences.
Our product	Empowers end users to streamline the process, significantly reducing the time required to develop reagents following

	genetic mutations. This automation enhances both efficiency and responsiveness in assay production.

2.5 Proposed New Process Flow

The BioBlade software system has been created to automate the process of gathering target (or pathogen) information and checking it against proprietary oligos. More concretely, BioBlade will automate steps 1, 2, and 3 from 1.2 Current Process Flow diagram. The system will automatically connect to public databases while accessing proprietary

The BioBlade software system exists with the goal of alleviating the tedious work required of the bioinformatician in the 1.2 Current Process Flow diagram. While the specific workflow will not change, the work previously required of the bioinformatician will be switched to the BioBlade system. See the diagram below for full process details:

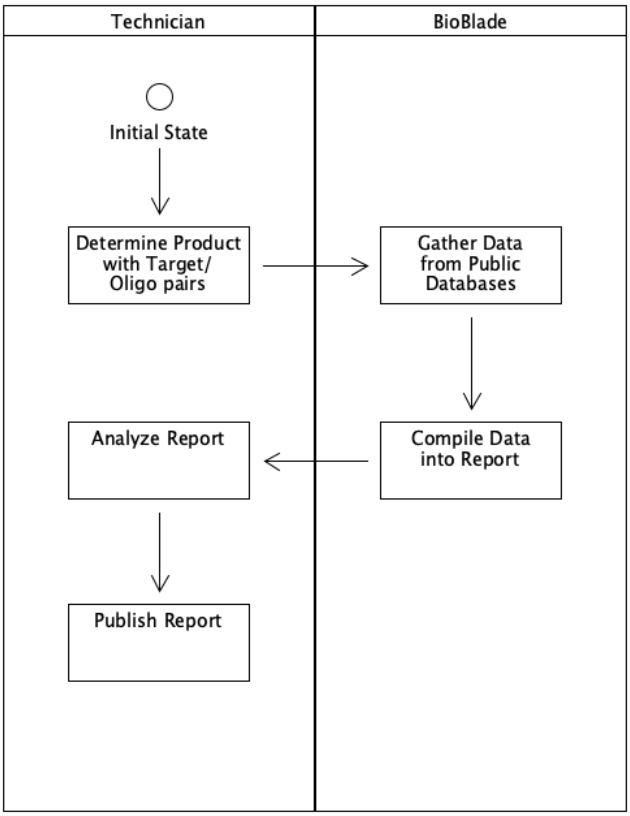

Figure (2) Proposed Process Flow

2.6 Business Risks

RI-1: Strict FDA and health regulations may limit the product's features or delay its release. Early consultations with experts on health regulations can ensure compliance from the beginning and prevent costly delays. (Probability = 0.7; Impact = 8)

RI-2: Inefficient querying of large databases could lead to delays in data retrieval, negatively impacting user experience and increasing infrastructure costs. Optimization of the database architecture early in the development process and caching solutions are necessary in order to be cost-effective. (Probability = 0.5; Impact = 7;)

RI-3: Software produces inaccurate or incomplete results, this could undermine the user trust, reduce adoption of the system, and expose the company to liability. (Probability = 0.1; Impact = 10)

2.7 Business Assumptions and Dependencies

AS-1: System with appropriate user interface will be available for FWDX employees to process comparisons between tests and sequences selected.

AS-2: Key target users will have the necessary technical infrastructure to use the product.

AS-3: The product will comply with all relevant industry regulations.

AS-4: User needs and preferences will remain stable during the product's development cycle.

DE-1: Integration with third-party APIs and services will be seamless.

DE-2: Sufficient budget allocation to cover unexpected expenses.

3. Stakeholder Profiles and User Descriptions

This section provides a profile of the stakeholders and users involved in the project, and the key problems that they perceive to be addressed by the proposed solution. It does not describe their specific requests or requirements as these are captured in a separate stakeholder requests artifact. Instead, it provides the background and justification for why the requirements are needed.

3.1 Stakeholder Summary

Stakeholder	Major value or benefit from this product	Attitudes	Major features of interest	Constraints	End user or not?
Jerry – Scientist & Co-Founder	Ability to identify deletions and mutations in the genetic sequences of diseases as soon as they happen, to determine if current tests are still effective.	Strong commitment to project and open to new ideas. Willing to provide necessary resources	Identifying deletions in genetic sequences	None Identified	Yes
Rabia – Operations and Regulatory	Ensure that FWDX's products are within FDA standards and regulations. Checking if tests are still effective allows these guidelines to be followed more closely	Believes the product could be useful to follow regulations, but may raise a red flag to regulatory bodies when first being used	Verifying that current tests are still accurate. Ensuring the product delivers accurate results on a consistent basis.	Need to ensure product stays within regulatory guidelines	No
Winnie – Quality Assurance	The quality of tests is directly tied to them being effective for the latest mutations and deletions.	Have not met yet.	Ensuring the product works correctly. Identifying which tests are no longer effective	Have not met yet.	No
Manuel – Bioinformatic-ian Consultant	No longer needs to manually look for deletions and mutations in genetic sequences. This takes about a week with the current process.	Demonstrates the current manual processes and provides example reports.	Automating a process that is done manually.	Time and funding; Bills FWDX hourly for work	No
Richie – Co-Founder & Commercial Operations	Increased sales; can market FWDX products as being more accurate and up-to-date than competitors	Have not met with yet. Jerry says he thinks it is a major business opportunity	Have not met yet.	Have not met yet.	No

3.2 User Environment

The BioBlade user base will be initially limited to FWDX Diagnostic. Users are defined as employees and supervisors within the FWDX Diagnostic organization who will be generating reports using the product to validate FWDX reagent efficacy against specific genetic sequences selected from a variety of diseases published in public databases. Access to the product will be reviewed on a case-by-case basis and access will be granted from within the organization.

3.3 Alternatives and Competition

There are no public offerings or alternative solutions. The current process entails a technical consultant creating a report, and then a biologist from FWDX Diagnostics would need to manually examine and compare the genetic strings from the database to find discrepancies. The other way is to buy another product from other companies, but these products are all developed for in-house use, and not available for sale.

Implementing this software will increase productivity and save time in the process of detecting the mismatch of new genetic sequences compared to those used for FWDX Diagnostics' products. FWDX Diagnostics supports developing the software from Texas Christian University's Senior Design class in order to reduce cost and maintain exclusivity rights over the product.

4. Scope and Limitations

This section provides a high-level view of the capabilities and constraints of the FWDX BioBlade system.

4.1 Product Perspective

The BioBlade system is created to automate an existing manual process; therefore, there are no systems in place that rely on the BioBlade system. This means the BioBlade system is functionally self-contained, and any interruption of service within the system will not have cascading effects on other systems.

The BioBlade system has two meaningful dependencies: the external health databases and proprietary sequences provided by the client. Without both of these inputs, the system will cease to function properly.

4.2 Major Features / Scope

FE-1: Automated comparison of genetic sequences.

> Given two sets of genetic sequences, BioBlade will be able to identify mismatches and deletions between the sequences. The system will be able to provide detailed location information for these changes, displayed to the user in an easily understood format. The client will be able to cancel the comparison check early if needed. The automated comparison will generate a human-readable report.

FE-2: Input of proprietary genetic sequences provided by the client.

> BioBlade will allow the client to import proprietary genetic sequences to build a repository of reagents used by FWDX. This repository can be used by the system when checking against other genetic sequences.

FE-3: Integration with national and international genetic sequence databases.

> BioBlade will be able to query a variety of national and international genetic sequence databases to provide the newest data to test against the proprietary genetic sequences. The system will be able to query all databases periodically.

FE-4: Periodic notification to the client of sequence mismatches.

> BioBlade will be able to automatically notify the client when mismatches are found between the proprietary sequences and the genetic sequences provided by the external databases. The cadence of these notifications can be modified by the client to differing intervals.

FE-5: Store collection of mismatch reports generated by the system.

> The BioBlade system will cache the results of previous genetic sequence checks to ensure that the same sequence pair is not checked more than once for mismatches. This also provides a report history to the client as needed.

4.3 Deployment Considerations

To be determined by Client as scope becomes clearer.

5. Other Product Requirements

RE-1: The product shall meet any applicable standards set by regulatory bodies related to the area of interest (i.e. FDA). These specific requirements can be gathered from Rabia, or will be defined later in the discovery.

RE-2: The product will locate deletions in a timely manner. When first computed for some disease, this process should not take more than 24 hours. After this, the product will only check new genetic sequences that have not been checked yet.

RE-3: The user will be able to check the product's correctness using test data to ensure deletions are identified correctly.

RE-4: The product will produce correct results 100% of the time whenever automated checks are performed. This is important to uphold the integrity of FWDX's products and to stay within regulatory guidelines.

RE-5: The product will pull data from a variety of databases for genetic sequences. These databases include (1) National Center for Biotechnology Information, (2) Global Initiative on Sharing all Influenza Data (GISAID), (3) SILVA rRNA Database, (4) SIB Swiss Institute of Bioinformatics ViralZone, (5) Bacterial and Viral Bioinformatics Resource Center (BV-BRC), (6) Eukaryotic Pathogen, Vector and Host Informatics Resource (VeuPathDB).

RE-6: The features included in this product and their usage shall be well-documented and easily accessible for end-users of the software.

RE-7: Any applicable backend systems shall be well-documented for future work to be done.