

Item #	User Needs Intended Uses	Design Inputs (Technical Requirement)	Acceptance Criteria		Design Outputs	Design Verification (Outputs = Inputs)	Design Validation (User Needs Met)
			M/Goal	Limit			
1.0 Customer Requirements (e.g. Functional)							
1.1	fast results	results display in X seconds			antibodies immediately in contact with food in compartment based on mechanism, results displayed as soon as possible	Testing protocols to analyze the speed and efficacy of the antibody test. Additionally the speed of the results being displayed will be analyzed in a separate protocol.	measure time between adding sample to the device and results being displayed for X trials of different food types and battery levels, time measured across all trials does not exceed the stated limit
1.2	easy to use	Average user can input and get results in X seconds; input volume less than X in^3; buttons to be pressed less than X; can be cleaned in X min; amount of instructions required for first use should be no more than X steps			"click" mechanism to input spoon and start reaction	Device drawings and testing protocol to analyze the "click" mechanism of inputting the spoon. Cyclic loading of different spoons into the device will also be tested.	test users operating the device without instructions are able to do so within stated time limit and report on a survey that using the device was not difficult
1.3	reliably detects gluten in prepared food	able to detect gluten at various levels in ppm (which is the unit for gluten measured), rate of false negatives is <x , rate of false positives is <x			antibody test/compartment within device. Alerts are displayed if there are any issues affecting the device's capability to detect gluten (ie insufficient sample, antibody test issues, cleaning issues, or defective spoon being used)	Testing protocol to analyze the accuracy of the antibody test and prevalence of false positive or negatives. Testing the speed of displaying alerts for various issues that may affect the accuracy of the antibody test.	clinical testing of substances that are known to contain or not contain gluten contamination shows that displayed results on device matches known result the stated proportion of the time
1.4	easy to understand results	user at seventh grade reading level can interpret results in x seconds. results can be read from up to X feet away in X nm of brightness			LCD screen with simple display	Display is tested in different brightness settings and with users of varying reading levels (7th grade or higher) to analyze if the simple display has interpretable results .	test users report on survey that they understand the results every time they used it
2.0 Product Performance Requirements (e.g. Mechanical)							
2.1	light-weight	weighs less than X pounds			lightweight materials chosen, weighs less than stated limit	Device and the various components are weighed	when weighed the device weighs than the stated limit, users report feeling comfortable carrying the device
2.3	long battery life, alert when low on battery	able to remain usable for X hours--when it is below X percentage a notification will be displayed			symbol on screen to indicate battery level	The device battery life is characterized using a voltmeter or multimeter. Additionally the battery level displayed is record to analyze if the display changes as the battery power becomes lower.	device battery lasts at least 24 hours and can perform at least 3 tests in that time frame, users do not report frustration with length of battery life
2.4	Easy to operate the different components of the device	Have a light that turns on in X sec when components are placed properly in the device. Have an alert that goes off in X second if sample size is insufficient, some component of the antibody test isn't working, removable components were not cleaned properly, or spoon is defective.			Light turns on if the inner components are placed correctly. Alert displayed if there is an insufficient sample, antibody test issues, cleaning issues, or defective spoon being used.	Protocol is implemented to check that the light turns on when the removable components are placed properly. Another protocol is performed to check that the applicable alerts are displayed for when there is insufficient sample, antibody test issues, cleaning issues, or defective spoon being used.	test users are able to operate it and put the components together without reporting significant difficulty, without instructions, and without seeing the device used by someone else
3.0 Biocompatibility Requirements							
3.1	will not contaminate food that is being tested	there is not an x amount of change of mass in food composition			new, clean spoon is used each time, device and antibodies do not come into contact with the rest of the meal	Device drawings that show that the antibodies are contained in the device and are not placed in contact with the larger meal. Accelerated life and vibrations tests are conducted on the spoon to ensure the disposable spoon is sterile when it comes into contact with the meal.	reusable portion of device does come into contact with the entire meal, the meal is only touched by a new, clean spoon before each test
3.2	easy to clean	user can clean the entire thing in X minutes			smooth surfaces, compartment is removable and dishwasher safe	Removable components are subjected to humidity and temperature tests that simulates the same conditions of a dishwasher. Cyclic loading of these removable components is also conducted to assess the lifetime this component can be removed and placed back into device. Tolerances for material roughness is characterized.	users without instructions are able to clean the device within the stated time limit, upon being tested for gluten and bacterial contamination the device is negative after being cleaned

3.3	Safe for users - no adverse physical, chemical, electrical harm (i.e. radiation)	Radiation on contact less than X. Chemical on contact less than X. Material durability is X years and X stiffness. Electrical wiring are up to code, so that current is X amperes and will not harm users.			Label for the physical, electrical and chemical/radiation risks. Alert is displayed for when device is malfunctioning due to some mass/volume change in device's components that could cause physical, chemical, or electrical harm.	Protocols to analyze radiation and chemical contact are performed. The different materials composing the device undergo static loading tests to characterize durability and stiffness. The current generated from the electrical wiring is tested using a voltmeter. The speed of alerts being displayed that warn users of some type of user harm occurring is characterized.	materials used are confirmed to be safe for human contact by their chemical label, all electrical components are contained within insulating materials
4.0 Regulatory Requirements							
4.1	Clinically tested for gluten detection	used in X studies to prove that is compatible/reliable			device results are accurate to known gluten presence X% of the time	Clinical studies are conducted to assess the compatability and reliability of the device detecting gluten.	researchers formulate meals known to contain, be cross-contaminated with, and not contain gluten. each meal is tested 3 times and device results match predicted. study
4.2	food-safe	Less than x amount of chemical and physical byproduct from solution			device materials are not coated in toxic materials, and are non-toxic themselves	The toxicity of device materials is characterized. Vibrations, static loading, cyclic loading, and humidity and temperature tests are performed to analyze the chemical and physical byproduct from the device under various conditions.	the meal is tested after use of the device for metals and plastics and none are identified within the food
4.3	FDA approved	follows all regulations of X requirements/organization			device meets regulations of X	Device drawings, documentations, and testing	researchers follow protocols set by the FDA and receive approval for consumer use
5.0 Interfaces with Other Systems							
5.1	an app to read results / see detailed readings	the data is able to be found in X seconds on an external device (such as a smart phone)			bluetooth or wifi connection within device. Any technical issues with app either prompt user to follow certain instructions (ie restart phone) or bugs are sent to software team to be fixed.	Bluetooth and wifi connection are analyzed using relevant technical tests. The speed of technical issues prompting further instructions for users or being sent to software team is characterized. The speed of seeing results on external device is characterized.	users are able to locate, download, and operate app on their smartphone and report finding additional useful information on it when used with the device
5.3	standard charger	charges in X hrs			usb-c charger port and battery display	The speed of charging is analyzed. Device drawings from charging port and battery display.	the charging port on the device and both ends of the charger cable match the dimensions and electrical properties of USB-C chargers commonly found in other devices
6.0 Other							
6.1	low/no waste	device can be used without obviously degrading for X uses // generates less than X grams of waste per use			only the spoon component is disposable, the device itself is cleaned and reused	Conduct vibration testing to test the sterile packaging of the disposable spoon and to make sure the spoon performs do not wear down. Conduct cyclic loading and temperature and humidity tests to verify that the device can be reused for X uses.	the device is able to be used up to X times, and the battery maintains at least 24 hours per full charge for at least 2 years. all components are included in this except for the spoons.
6.2	can be carried in a purse/backpack	volume less than X in^3, dimensions less than X by X by X; weight less than Xlbs			The outer portion of the device resembles a normal thermos that can be carried in purse/backpack	Conduct cyclic loading and temperature and humidity tests to verify that the outer portion of the device resembles a thermos by the same X (volume, length, width, weight) even after X uses.	test users report on survey that they are comfortable transporting the device in public, and that it does not create additional burden in the form of another bag
6.3	quiet/low profile (not disruptive in public space)	noise level less than X decibals			The outer portion of the device resembles a thermos and noise generated is minimal.	Conduct accelerated life test to determine the X uses the device can used so that the noise level is less than X decibels	noise made by device (putting components together, test running, results displaying) does not exceed stated volume in testing. users do not report embarrassment when testing the device in a public place
6.4	tests the entire meal for contamination	concludes if gluten is present in up to X grams (X cups/ounces) of food, minimum amount of food is X grams/cups			Device display's if gluten is present or not.	Clinical tests are conducted to verify the gluten tolerances the device detects for a sample of X grams/cups/ounces	test meal is created such that certain components are known to be contaminated, but not others, and another such that one location is contaminated but not the rest. device displays positive results for these meals when user tested
6.5	can test both solid and liquid food, both hot and cold	able to detect gluten in liquid of X viscosity range, X density range // able to function on food within X-X degrees F			spoon (holds liquid) and has spikes for collecting solid, material does not melt/react to high/low temperatures. Label for the maximum and minimum temperature the device can handle.	Clinical tests are conducted to verify that the device detects gluten in liquid of X viscosity, X density, X - X degree range	meals are created (both with and without contamination) of liquid foods like soup or smoothies and solid foods like sandwiches, pasta, and cake. meal temperature is also varied between stated limits. device results matches predicted results when tested by users. users are able to clean the device and use it for a new sample afterwards.
6.6	Health data is secure	The results/ data generated is not stored on any server or platform for more than X mins.			There are multiple firewalls and protection programs embedded into the device and app to make the sure the results are secure.	Third parties evaluate the software systems of the device to establish that the results/data generated are not stored on any server or platform for more than X mins	app is encrypted and does not collect user location data. communication between device and app is also secure.