

Revision	Date	Team Members	Description of Change
1	3/10/23	All	Creation of risk analysis, risk control, risk/ benefit analysis, information/comments
2	3/27	All	

Severity Ratings	Description	Example	Occurrence Ratings	Description	Example
5 catastrophic		severe allergic reaction due to high gluten levels undetected (above X ppm)	5 frequent		nearly always (<95% of the time)
4 critical		moderate allergic reaction due to moderate gluten undetected (X-X ppm gluten)	4 probable		very likely (50-95% of the time)
3 serious		minor allergic reaction due to cross-contamination undetected (0-Xppm)	3 occasional		likely (10-50% of the time)
2 minor		unclear results, food not eaten out of caution	2 remote		unlikely (1-10% of the time)
1 negligible		false positive, food not eaten	1 improbable		almost never (<1% of the time)

Item Number	Function	Risk Analysis							Risk Control				Risk/Benefit Analysis	Information/Comments	
		HAZARD (Potential cause of Hazard)	Hazardous Situation	HARM (Potential adverse effect)	Cause	SEVERITY	OCCURRENCE	RPN	RISK MITIGATION	SEVERITY	OCCURRENCE	RPN			Risk reduced as far as possible? (afap)
1	Chemical Contamination	Device emits harmful chemicals	Harmful chemicals injected	User has a reaction to injecting toxic chemicals	Material deteriorates or malfunctions	5	1	5	Material specification on the biocompatibility	5	1	5	afap	Yes	Label for chemical risk
2	Unclear Display	Device inaccurately does not detect gluten or shuts off in the middle of analyzing the sample	False negative result displayed	User has reaction after eating the contaminated food	Low power or device performing antibody test malfunctions	5	2	10	Alert when power is low clearly on display for user in place of results	4	1	4	afap	Yes	Manual of alerts
		food denatures antibody	false negative result displayed	User has reaction after eating the contaminated food	food is too hot	5	2	10	device label indicates maximum functional temperature of food input	5	1	5	afap	Yes	label on device w/ antibody functional range
		Device is not useful for users to detect gluten	User does not eat the food out of caution as the results are unclear	User cannot see result	Outside Brightness cause the display to be unclear	2	2	4	Design the display screen to be readable in a variety of brightness settings.	2	1	2	afap	Yes	
		Removable compartment or spoon inserted back into device incorrectly	Device does not process food	User does not get accurate results	User error	2	2	4	Alert when components in device are not placed properly and have a light that turns on when components are placed properly in the device. cap cannot be secured unless pushed all the way down onto spoon to release antibodies (spoon must be placed correctly, with wide side down), cap also must be correctly secured for antibodies to be released. antibodies not released unless pod is secured in cap correctly. alert if no antibodies/insufficient antibodies.	2	1	2	afap	Yes	Manual of alerts
3	Electrical Shock	Device produces current in the wrong location	Electrical current exposed	User gets minorly electricuted	Electrical malfunction	4	1	4	Ensuring all electrical codes are met: including proper covering of all wires	4	1	4	afap	Yes	Label for electrical shock risk
4	Physical Contamination	Device material breaks off and creates small fragments	Small fragement ingested which harms the digestive system	Fragment causes blockage requiring surgery	Material is not durable or user uses too much force	3	1	3	Material specification on durability and flexibility of material	3	1	3	afap	Yes	Label for material damage risk
5	False Negative	Antibody test not working correctly	Gluten-containing food injected	User is unable to obtain results	Insufficient amount of sample provided or antibodies not working properly	5	2	10	Alert to user when sample does not meet a minimum weight or that antibody test isn't working. alert shows up in place of results (same spot on screen)	5	1	5	afap	Yes	Manual of alerts
			Insufficient antibodies	User is unable to obtain results	Mechanical Error	5	2	10	Alert to user when there are insufficient antibodies. alert appears instead of results in the same spot	5	1	5	afap	Yes	Manual of alerts
		not cleaned correctly	Food contains gluten but system indicates that there is not gluten	User has reaction after eating the contaminated food	User error	5	2	10	Alert user when the device hasn't been cleaned properly (alert in same spot as where results would be). device's might of light-colored, smooth materials so major contamination is easily visible.	5	1	5	afap	yes	Manual of alerts
		Spoon does not test entire meal	User does not swipe through entire meal	User has reaction after eating the contaminated food	User error	5	2	10	Alert user when spoon is defective and sample collected does not meet minimum weight. alert takes place of results on screen	5	1	5	afap	yes	Manual of alerts
		Spoon does not test entire meal	The spoon does not collect the correct viscosity of the food	User has reaction after eating the contaminated food	Mechanical Error	5	2	10	Alert user when spoon is defective and sample collected does not meet minimum weight. alert takes place of results on screen	5	1	5	afap	yes	Manual of alerts
6	Slow results	Device detects gluten slowly	User eats food despite unknown result	User has reaction after eating the contaminated food	Low power or device performing antibody test malfunctions	5	2	10	Alert when power is low clearly on display for user and alert if device or parts of the device require replacements. alerts take place of results on screen	5	1	5	afap	yes	Manual of alerts
7	No results	No battery power	user is unsure if food is safe	user does not eat food user eats cross-contaminated food due to lack of restuls	device does not alert user that battery is low	5	3	15	alert when battery is only operable for 1 more hour, device is fully operable during this hour. both positive and negative results have lit-up screen display while dead battery has a blank screen (easily differentiable)	5	1	5	afap	yes	Manual of alerts
8	False Positive	not cleaned correctly	Food does not contain gluten but system indicates that there is	User does not eat food	Prior contamination from previous sample	1	3	3	Alert when device components have not been cleaned properly (alert in place of results). materials chosen are easy to clean and asses visually	1	1	1	afap	yes	Manual of alerts

9	chemical contamination	contamination from product	Food is not safe for consumption due to battery but no notice is given	user eats contaminated food	Device materials malfunction or deteriorate	5	2	8	Alert when device components mass/volume has changed or device is malfunctioning. alert takes place of any results	4	1	4	afap	yes	Manual of alerts and label for chemical risk
10	User injected induced injury	User mishandles device	Small fragment cuts the skin	User is physically hurt and could require stitches or surgery	User error	3	2	6	Alert when device components mass/volume has changed or device is malfunctioning. Also have manual on how to properly use the device. alert takes place of results	3	1	3	afap	yes	Manual of alerts and instructions on how to use device. Label for material damage risk
		Material Breaks	Small fragment ingested which harms digestive system	Fragment causes blockage requiring surgery	Mechanical Error	5	3	15	Alert when device components mass/volume has changed or device is malfunctioning. alert in place of results	5	1	5	afap	yes	Manual of alerts. Label for material damage risk
11	Devices makes loud noises	System creates noise through different functional processes	User is embarrassed, device is not used	User eats contaminated food	alerts/results are loud/distracting	5	5	25	limit amount of sounds made, limit volume of sounds. spoon and device shapes chosen to blend in with user setting	1	1	1	afap	yes	
12	Inconsistent accuracy of results	incorrect results	device is not reliable	user does not trust results	not sufficiently tested	5	3	15	Thorough clinical testing is implemented by third parties. And robust verification and validation testing is done as well.	5	1	5	afap	yes	
13	users with lower gluten tolerances react more often	gluten present, but below test threshold	displays negative results	user has a reaction despite true negative	not sufficiently tested	3	2	6	Thorough clinical testing is implemented by third parties and label with minimum amount of gluten the device detects is added onto the device	3	1	3	afap	yes	Label with the risks of using the device
14	antibodies unable to bind to food	food is too hard/solid	displays negative results	user may consume contaminated food	test is not functional on all food types	5	1	5	testing is done with a variety of food textures	5	1	3	afap	yes	
15	liquid food leaks into another compartment of device	inner compartment not sealed correctly	damage to inner mechanisms	device cannot be used again	compartment not built to hold liquids	2	3	6	water-tight seal around inner compartment	2	1	3	afap	yes	
FINAL			Overall Residual Risk is Acceptable (Yes/No):											Yes	