Development and Validation Questionnaire for Medication Safety Perceptions Among Lactating Mothers: A Rasch Analysis

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Abstract: *Medication safety during lactation is a significant concern in community pharmacy and public health. Medicine have potential risk to infant health via breast milk. Mother perceptions of medication safety during lactation remains crucial. This study aimed to develop and validate a questionnaire to assess mothers' perceptions of medication safety during lactation using the Rasch measurement model. A cross-sectional study was conducted in breastfeeding mothers from Banyumas City, Indonesia. A two-step approach was used: item generation and validation through expert review. Rasch analysis, conducted using Winsteps software, evaluated the instrument's psychometric properties, including item difficulty and person ability, based on the Rasch model. This study enrolled 126 participants and the study revealed 15 items have strong psychometric properties, with high internal consistency (Cronbach's alpha = 0.94) and unidimensionality (55.2% variance explained). Rasch analysis confirmed the validity of the instrument, with 15 items achieved the thresholds except for item P13, which was removed due to misfit. The instrument successfully distinguished between varying levels of respondent ability, confirming its reliability and suitability for measuring medication safety perceptions during lactation. The developed instrument provides a reliable and valid tool for assessing mothers' perceptions of medication safety during lactation. While this instruments demonstrates strong psychometric properties, further refinement was needed, particularly for misfitting items. Future research should focus on expanding the sample size and validating the instrument across diverse populations.*

Keywords: *Medication, Perception, Psychometrics, Questionnaire*

1. INTRODUCTION

Medication safety during lactation is a critical concern in clinical pharmacy and public health [1]. The transfer of active pharmaceutical ingredients into breast milk can pose pharmacological or toxic risks to infants [2]. The increasing rates of medication use among breastfeeding mothers for both acute conditions like infections and chronic diseases such as hypertension and diabetes [3]. Studies globally show that a significant proportion of breastfeeding mothers use medications, but this raises concerns about the safety and appropriateness of such treatments [4].

The use of medications during lactation is a common yet complex issue. Research from various countries, including Denmark [5], Saudi Arabia [6], and Macau [7], has shown that many breastfeeding mothers consume medications, including traditional remedies, despite the lack of adequate information to make informed decisions. These studies highlight the gap in available resources and information for mothers regarding medication safety during breastfeeding. Furthermore, psychosocial factors play a crucial role in shaping mothers' decisions on medication use [8].

Mothers' perceptions of medication safety significantly influence their healthcare decisions, where negative perceptions can result in avoidance of necessary medications, while misconceptions may lead to inappropriate self-medication [9], [10]. Factors like education level can further shape these perceptions [11]. Previous studies have highlighted the importance of understanding these perceptions, but most have been descriptive in nature and lacked the use of psychometrically validated tools [12]. Consequently, a reliable, valid

instrument to measure mothers' perceptions of medication safety during lactation is essential for informing healthcare practices and policies [13].

This study aimed to develop and validate an instrument to assess mothers' perceptions of medication safety during lactation using the Rasch model. The Rasch model provides a robust methodological framework that overcomes the limitations of classical test theory (CTT), offering precise item measurement and ensuring the validity and reliability of the tool [14].

2. METHOD

This study adapted the approach used by previous studies, including those in China [7], Indonesia [15], and Saudi Arabia [6], which involved the development of questionnaires for measuring mothers' perceptions of medication safety during lactation. The content of the questionnaire was also informed by two theoretical frameworks [16], [17]. The development process followed a two-step approach: (1) item generation and instrument formation, and (2) validation through face and content validity testing.

Ethical approval for this study was granted by the Health Research Ethics Committee of Universitas Harapan Bangsa (B.LPPM-UHB/1332/12/2025) in December 2025. All participants were provided with detailed information about the study and gave their written informed consent. Anonymity was assured to protect participant identities.

The MEDLACT-Q (Medication Lactation Questionnaire) instrument was developed through a three-step process: Item development, Face content validity, under the participants. The content domain was defined based on a thorough review of the literature to identify relevant variables. The final version of the instrument was reviewed and approved by the research team, and 17 items were selected.

Face validity was assessed by an expert panel consisting of both content and lay experts. Experts evaluated each item for relevance, clarity, and simplicity using a four-point Likert scale: relevance (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree) and clarity (1 = not clear, 2 = needs revision, 3 = clear with minor revisions, 4 = very clear). The content validity index (CVI) was calculated using both the Item-CVI (I-CVI) and Scale-CVI (S-CVI) methods. Items with an I-CVI above 0.79 were considered relevant. The S-CVI/Ave value was calculated to assess the overall content validity, with an acceptable threshold of 0.90 for excellent content validity.

This study employed a quantitative approach with a cross-sectional survey design, involving breastfeeding mothers from Banyumas City, Indonesia, with a total population of 54,342 people. Inclusion criteria were: (1) mothers with children aged 0-24 months, (2) mothers attending activities, (3) mothers willing to participate, and (4) mothers who were able to read and write. Exclusion criteria included unwillingness to complete the questionnaire and incomplete responses. The survey was conducted offline in the field using paper questionnaires, and participants were given 5-10 minutes to complete the questionnaire.

The sample size of 126 participants was considered adequate for Rasch analysis, as previous methodological studies suggest that a minimum of 100–150 respondents is sufficient to obtain stable item parameter estimates and reliable measurement calibration. Data collection was conducted offline at mother breast facilities in Banyumas. Eligible participants were approached directly by trained data collectors during routine lactation sessions. After obtaining informed consent, participants were provided with a paper-based questionnaire and given approximately 5–10 minutes to complete it independently. Data collectors remained available to clarify questions without influencing responses. Completed questionnaires were checked for completeness on-site before data entry.

The psychometric properties of the MEDLACT-Q instrument were evaluated using the Rasch measurement model. Data analysis was conducted using Winsteps software with a logit scale. The Joint Maximum Likelihood Estimation (JMLE) equation was applied to assess the model fit. Rasch analysis was used to evaluate the scale's measurement properties, including the difficulty of each item and its ability to measure the intended construct. Rasch modeling is a widely used method in health and education for evaluating the psychometric qualities of scales and questionnaires. Winsteps software was used to execute the analysis, and the results were interpreted to assess the scale's validity and reliability

3. RESULTS AND DISCUSSION

This study is the first to apply the Rasch measurement model to develop and evaluate an instrument designed to assess mothers' perceptions of medication safety during lactation. Conducting psychometric analysis. Unlike traditional item response theory, which correlates respondents' abilities with the likelihood of selecting

more difficult items. The instrument demonstrated strong psychometric properties, with unidimensionality, indicating all items measure mothers' perceptions of medication safety during lactation. This unidimensionality was confirmed by the of variance explained by the measure, which exceeds the threshold required for Rasch-based evaluations, consistent with findings from previous study in Greece [21]

The face and content validity were conducted to ensure that only relevant variable selected and included in the structure of the draft instruments. **Table 1** presented five experts consisting of two pharmacists, two public health experts, and one maternal health practitioners evaluated the instrument. Fifteen items achieved perfect agreement among experts (I-CVI = 1.00), while one item showed acceptable agreement (I-CVI = 0.80). Two items (P6 and P8) obtained lower I-CVI scores of 0.60, indicating partial agreement among experts. Overall, the average proportion of items judged as relevant across the five experts ranged from 0.75 to 0.85, with an average S-CVI of 0.80, indicating satisfactory content validity for the MEDLACT-Q instrument.

Table 1. Content validity of MEDLACT-Qinstruments

Variable	Panel 1		Panel 2		Panel 3		Panel 4		Panel 5		Expert in Agreements	I-CVI Score	S-CVI Score
Construct	n	Code	n	Code	n	Code	n	Code	n	Code			
P1	4	1	4	1	4	1	4	1	4	1	5	1.00	1
P2	4	1	4	1	4	1	4	1	4	1	5	1.00	1
P3	4	1	4	1	3	1	4	1	3	1	5	1.00	1
P4	4	1	4	1	4	1	4	1	4	1	5	1.00	1
P5	4	1	4	1	3	1	4	1	3	1	5	1.00	1
P6	3	1	2	0	3	1	2	0	3	1	3	0.60	0
P7	4	1	4	1	4	1	4	1	4	1	5	1.00	1
P8	4	1	2	0	4	1	2	0	4	1	3	0.60	0
P9	4	1	4	1	4	1	4	1	4	1	5	1.00	1
P10	3	1	4	1	3	1	4	1	4	1	5	1.00	1
P11	4	1	4	1	4	1	3	1	4	1	5	1.00	1
P12	4	1	4	1	3	1	4	1	4	1	5	1.00	1
P13	4	1	3	1	4	1	4	1	4	1	5	1.00	1
P14	4	1	4	1	4	1	3	1	4	1	5	1.00	1
P15	4	1	3	1	1	0	4	1	3	1	4	0.80	1
P16	4	1	4	1	4	1	3	1	4	1	5	1.00	1
P17	4	1	4	1	4	1	4	1	3	1	5	1.00	1
Mean		**0.850**		**0.750**		**0.800**		**0.750**		**0.850**	**Summary**	**16.00**	**15.00**
Average proportion of items judged as relevance across the 5 experts											**Average**	**0.80**	**0.75**

This study enrolled 126 participants from from community health posts in Banyumas. **Table 2** provided the samples were recruited by using convenience sampling. In this study, there were participants from each health posts for the analysis Of the total sample, 42.1% were 26-35 Years, 50.8% were Senior High School, 65.1% were have Child 13-24 Months, 42.1% ≥3 Children, and 50.8% were never use medication when during lactatation.

Table 2. Demographic characteristics of the participants (*N* = 126).

Characterisrics	Frequency	%
Age		
16-25 Years	39	31.0%
26-35 Years	53	42.1%
36-45 Years	26	20.6%
>45 Years	8	6.3%

Characterisrics	Frequency	%
Educational Level		
Elementary sschool	18	14.3%
Junior High School	34	27.0%
Senior High School	64	50.8%
Bachelor	6	4.8%
Master/Doctoral	4	3.2%
Child Age		
0-12 Months	44	34.9%
13-24 Months	82	65.1%
Number of Children		
1	30	23.8%
2	43	34.1%
≥3	53	42.1%
Last Medication Use		
<1 Month	33	26.2%
>1 Month	29	23.0%
Never	64	50.8%

The psychometric properties of the developed instrument based on the Rasch measurement model were analyzed. Winsteps runs analyses was based on Joint Maximum Likelihood Estimation (JMLE) equations. In this formulation, the raw data were converted to interval data (logit) [18]. The logit scale can express a person's ability and item difficulty ranging from positive to negative infinity. The 15 item M were analyzed as two-facet items and person models using the Rasch measurement with the Winsteps software [19]; fit indices for the items included in the model as presented in **Table 3.**

Table 3. The summary statistics of Rasch parameters for MEDLACT-Q

Criteria	Person	Item (Question)
N	126	15
Mean		
Infit MNSQ	1.04	1.0
Infit ZSTD	-0.2	0.0
Outfit MNSQ	1.12	1.12
Outfit ZSTD	-0.2	0.5
Reliability (Rasch)	0.87	0.96
Reliability (Cronbach's alpha)	0.94	
Separation coefficient	2.56	5.05
Unidimensionality		
Raw variance by measure	55.2%	
Unexplained variance in 1st contrast	3.8%	

MNSQ = mean square, ZSTD = z-standard

The observed raw variance explained by the measure was 55.2%, while the unexplained variance was 3.8%. The instrument can reach unidimensionality when the measure explains more than 50% of the raw variance [18], [20]. The means of infit (weight) and outfit (unweight) mean square (MNSQ) for the respondents were acceptable, with values of 1.04 and 1.0, respectively, while thoseof z-standard (ZSTD) were also acceptable, with values of -0.2 and -0.2, respectively. Meanwhile, infit and outfit MNSQ for items were 1.0 and 1.12, respectively, while thoseof infit and outfit ZSTD were 0.0 and 0.5, respectively.

Table 4. Item fit statistics for MEDLACT-Q items (n = 126)

Item	INFIT		OUTFIT		PTMEA CORR
	MNSQ	ZSTD	MNSQ	ZSTD	
P13	1.26	1.90	2.09	5.70	0.52
P12	1.08	0.60	1.53	3.10	0.57

P11	1.19	1.50	1.46	2.90	0.59
P15	1.15	1.10	1.42	2.30	0.56
P10	1.15	1.20	1.20	1.50	0.64
P14	1.06	0.50	1.20	1.20	0.59
P1	1.10	0.80	0.98	-0.10	0.73
P9	1.02	0.20	1.04	0.30	0.66
P7	1.01	0.10	1.02	0.20	0.68
P3	0.97	-0.20	0.90	-0.70	0.72
P2	0.92	-0.60	0.86	-1.00	0.75
P4	0.80	-1.60	0.75	-2.00	0.77
P5	0.80	-1.70	0.79	-1.00	0.74
P8	0.76	-2.00	0.76	-1.90	0.72
P6	0.73	-2.40	0.76	-1.90	0.73

Figure 1 presented a wright map while the right side of the map shows the 15 items of the MEDLACT-Q, ranging from the easiest (P1, bottom) to the most difficult (P15, top). The left side represents participants' agreement levels, with the measure of participant agreement aligned with the item difficulty level. The letter "M" on the left and right sides indicates the average item difficulty and the average participant agreement, respectively. The closer the location of M is to both measures, the better the fit between the item and the participant. Each 'X' represents one participant, with "T" indicating the difficulty threshold.

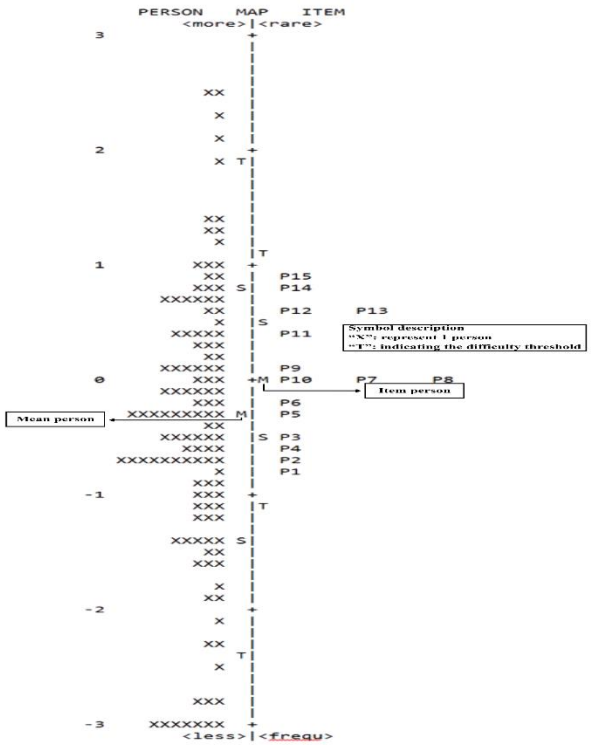

Figure 1. Wright map (item–person correlation).

Most items in the instrument showed good fit indices, aligning with standard Rasch thresholds. However, item P13 showed misfit with MNSQ values above the threshold, indicating that this item may not

perform as expected across the sample. This result is consistent with findings from other Rasch-based studies, where misfitting items were identified and subsequently removed to improve instrument validity [21]. The reason for this misfit could be due to the item's complexity or lack of relevance to certain respondents.The remaining items fit the Rasch model well, confirming the instrument's robustness and its ability to reliably measure the intended construct. Item P13 exhibited misfit with MNSQ values exceeding the acceptable threshold, suggesting that it may not perform as expected across the sample; however, its inclusion could still be justified, as it may capture variability in perceptions that other items do not, requiring further review rather than removal at this stage [22]. After excluding P13, the remaining items demonstrated a good fit, confirming the robustness of the instrument [23].

The unidimensionality assumption was thoroughly tested and confirmed, with 55.2% of the variance explained by the latent trait, which is above the minimum requirement for Rasch analysis. This result is consistent with other Rasch-validated instruments, such as the AKAQ (Antibiotic Knowledge Assessment Questionnaire), which also demonstrated unidimensionality and reliability [24]. The separation coefficient values for persons (2.56) and items (5.05) indicate that the instrument is effective in distinguishing between participants of varying ability levels and measuring the difficulty of each item effectively. The high Cronbach's alpha value (0.94) further confirms the internal consistency of the instrument, aligning with standards set by other validated scales in healthcare [25].

Study in Uganda [26] reported a 78.9% prevalence of medication use during breastfeeding, our findings show a similar prevalence rate, emphasizing the widespread use of medications among breastfeeding mothers. However study in Uganda [26] focused on self-medication, our study specifically assesses mothers' perceptions of medication safety during lactation using this instrument, offering a more nuanced perspective on breastfeeding mothers' attitudes and concerns. Moreover, study in Greece [21] conducted a study on medication safety during lactation using pharmacovigilance data. Similarly, our study utilized LactMed and Hale's Lactation Risk Category to evaluate the safety of medications for breastfeeding mothers. Both studies underline the importance of evidence-based resources in promoting safe medication practices for lactating mothers. The application of Rasch analysis in both studies further reflects the growing trend of using advanced psychometric methods to validate health related questionnaires, ensuring the precision and reliability of the instruments used in clinical and research settings [27].

From a clinical perspective, the validated MEDLACT-Q provides a structured tool that can be used by healthcare professionals, particularly pharmacists and maternal health practitioners, to assess mothers' perceptions regarding medication safety during lactation. This is important because misperceptions may lead to inappropriate medication use, including unnecessary avoidance of essential therapies or unsafe self-medication practices. By identifying perception gaps, the instrument can support targeted educational interventions and counseling strategies in primary healthcare settings, such as hospital or community pharmacies.

Although the MEDLACT-Q instrument demonstrated strong psychometric properties, there are some limitations in this study. The sample size of 126 participants limits the generalizability of the findings to broader populations, particularly in other regions of Indonesia or internationally. Additionally, misfitting items (e.g., P13) were identified, indicating the need for further refinement of the instrument in future studies. Furthermore, the study was conducted in Banyumas City, which may limit the applicability of the findings to other urban or rural areas. Future research should focus on expanding the sample size, incorporating participants from diverse regions, and exploring the inclusion of additional constructs related to medication safety during lactation. Longitudinal studies could also investigate the test-retest reliability of the MEDLACT-Qand its responsiveness to changes in mothers' medication use over time.

4. CONCLUSION

The MEDLACT-Q successfully developed and validated using the Rasch measurement model. The study's findings underscore the importance of using evidence-based resources like LactMed and Hale's Lactation Risk Category. Future studies should focus on expanding the sample size and including diverse populations to enhance generalizability and explore the instrument's responsiveness to changes over time.

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REFERENCES

[1] J. P. Spencer, S. Thomas, and R. H. T. Pawlowski, "Medication safety in breastfeeding," *Am. Fam. Physician*, vol. 106, no. 6, pp. 638–644, 2022.
[2] H. Szyller *et al.*, "Bioactive components of human milk and their impact on child's health and development, literature review," *Nutrients*, vol. 16, no. 10, p. 1487, 2024.
[3] L. Sportiello and A. Capuano, "It is the time to change the paradigms of pregnant and breastfeeding women in clinical research!," *Front. Pharmacol.*, vol. 14, p. 1113557, 2023.
[4] WHO, "breastfeeding mothers use at least one type of medication." Accessed: Oct. 31, 2025. [Online]. Available: https://www.who.int/news-room/questions-and-answers/item/breastfeeding
[5] D. R. Gotfredsen, I. M. Heerfordt, C. Storm Baden, H. Horwitz, C. Gade, and J. T. Andersen, "Prescription drug use in breastfeeding mothers and infant exposure: A register-based cohort study," *Br. J. Clin. Pharmacol.*, 2025.
[6] N. A. Alhajri *et al.*, "Women's Perceptions of Medication Use During Pregnancy and Breastfeeding in Saudi Arabia," *Cureus*, Dec. 2022, doi: 10.7759/cureus.32953.
[7] T. Zheng, W. Chen, H. Hu, Y. Wang, J. E. Harnett, and C. O. L. Ung, "The prevalence, perceptions and behaviors associated with traditional/complementary medicine use by breastfeeding women living in Macau: a cross-sectional survey study," *BMC Complement. Med. Ther.*, vol. 20, no. 1, p. 122, Dec. 2020, doi: 10.1186/s12906-020-02921-8.
[8] K. M. Renbarger, B. Phelps, A. Broadstreet, and S. Abebe, "Factors associated with maternal engagement in infant care when mothers use substances," *Womens Health Rep.*, vol. 4, no. 1, pp. 48–64, 2023.
[9] H. Ghorbani, A. Ghahramanian, A. Davoodi, L. Valizadeh, and F. Bagheriyeh, "Iranian mothers' perceptions of key nursing safety practices during first chemotherapy treatment of children with leukaemia: a longitudinal study," *BMJ Open*, vol. 15, no. 9, p. e101161, 2025.
[10] J. M. Taber, B. Leyva, and A. Persoskie, "Why do people avoid medical care? A qualitative study using national data," *J. Gen. Intern. Med.*, vol. 30, no. 3, pp. 290–297, 2015.
[11] B. Beggs, L. Koshy, and E. Neiterman, "Women's perceptions and experiences of breastfeeding: a scoping review of the literature," *BMC Public Health*, vol. 21, no. 1, p. 2169, 2021.
[12] K. Swan *et al.*, "Measuring what matters in healthcare: a practical guide to psychometric principles and instrument development," *Front. Psychol.*, vol. 14, p. 1225850, 2023.
[13] A. Bednarek, I. Bodys-Cupak, A. Serwin, and E. Cipora, "Mothers' attitudes towards breastfeeding in terms of health safety and professional lactation education: a national survey of women," *J. Multidiscip. Healthc.*, pp. 3273–3286, 2023.
[14] T. G. Bond and C. M. Fox, *Applying the Rasch model: Fundamental measurement in the human sciences*. Psychology Press, 2015.
[15] D. A. Kurniasih, C. S. Salasanti, and L. Aprilia, "Gambaran Persepsi Ibu Hamil Tentang Keamanan Obat Selama Kehamilan di UPT Puskesmas Puter Kota Bandung," *Maj. Farmasetika*, vol. 4, Jan. 2020, doi: 10.24198/mfarmasetika.v4i0.25874.
[16] T. L. DiPiro, J. T. Schwinghammer, V. L. Ellingrod, and C. V. DiPiro, Eds., *DiPiro's pharmacotherapy handbook*, Twelfth edition. New York: McGraw Hill Medical, 2023.
[17] T. W. Hale, K. Krutsch, and others, *Hale's Medications & Mothers' Milk 2025-2026: A Manual of Lactational Pharmacology*. Springer Publishing Company, 2024.
[18] M. Planinic, W. J. Boone, A. Susac, and L. Ivanjek, "Rasch analysis in physics education research: Why measurement matters," *Phys. Rev. Phys. Educ. Res.*, vol. 15, no. 2, p. 020111, 2019.
[19] S. Soeharto and B. Csapó, "Evaluating item difficulty patterns for assessing student misconceptions in science across physics, chemistry, and biology concepts," *Heliyon*, vol. 7, no. 11, 2021.
[20] M. Heene, "Applying the Rasch model: fundamental measurement in the human sciences," 2020.
[21] T. Maria, N. Christina, L. Aikaterini, and M. Dimitra, "Medication Safety in Breastfeeding Mothers. The Current Situation in the Greek National Healthcare System," 2023.

[22] D. M. Bond, J. M. Morris, and N. Nassar, "Study protocol: evaluation of the probiotic Lactobacillus Fermentum CECT5716 for the prevention of mastitis in breastfeeding women: a randomised controlled trial.," *BMC Pregnancy Childbirth*, vol. 17, no. 1, p. 148, May 2017, doi: 10.1186/s12884-017-1330-8.
[23] K. A. Bollen, "When good loadings go bad: Robustness in factor analysis," *Struct. Equ. Model. Multidiscip. J.*, vol. 27, no. 4, pp. 515–524, 2020.
[24] I. Y. Kusuma *et al.*, "Antibiotic knowledge assessment questionnaire in undergraduate pharmacy students: A Rasch analysis of validity evidence," *Pharm. Educ.*, vol. 24, no. 1, pp. 54–78, 2024.
[25] R. J. Bennett, J. Larsson, S. Gotowiec, and M. Ferguson, "Refinement and validation of the empowerment audiology questionnaire: Rasch analysis and traditional psychometric evaluation," *Ear Hear.*, vol. 45, no. 3, pp. 583–599, 2024.
[26] R. Nakijoba *et al.*, "Prevalence, safety evidence, and determinants of medicine use during breastfeeding among women in Kampala, Uganda," *BMC Womens Health*, vol. 25, no. 1, p. 387, 2025.
[27] S. Roy, B. Mandal, and B. K. Das, "Ensuring Precision, Reliability, and Compliance," *Lab. Tech. Fish Dis. Diagn.*, p. 79, 2025.