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Evaluation Study for Reference Interval of UF-1000*i* Using Urine Specimens from Schoolchildren

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Using the fully automated urine particle analyzer UF-1000i, examination was carried out for finding the reference interval of urine sediment in schoolchildren (7 to 15 years old) . As a result, we obtained the upper limit of a child's reference interval by gender. This is valuable data as reference information.

Key Words Urine Sediment, Fully Automated Urine Particle Analyzer, UF-1000*i*, Reference Interval, Schoolchildren

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INTRODUCTION

The clinical reference intervals for laboratory tests on children change with age and are often different from those of adults. Although there have been requests in each of the institutions for setting the reference intervals for children, it is not easy to collect sufficient data on healthy children, while following the Clinical and Laboratory Standards Institute (CLSI) guidelines, and not many reports are available. In Japan, urinalysis is part of health checkup in primary and middle schools. The situation would be even more difficult in other countries where no such system is in place. Sometimes the criteria for urinalysis in schoolchildren are different from those set by the Japanese Committee for Clinical Laboratory Standards (JCCLS)[1]. Therefore, it would be useful to examine the reference intervals in children.

The fully automated urine particle analyzer UF-1000*i* of Sysmex (hereinafter, UF-1000*i*) is based on the principle of flow cytometry, and is a urine screening device that can quantitatively and automatically analyze different particles in urine. Quantitative values of the analysis parameters (red blood cells (RBC), white blood cells (WBC), epithelial cells (EC), casts (CAST), and bacteria (BACT)) can be obtained in a short time using uncentrifuged urine samples[2]. The reference intervals for urine specimens of adults who had undergone wellness screening had been examined earlier with this analyzer[3]. In the present study, we undertook an investigation with urine specimens of schoolchildren.

SUBJECTS AND METHODS

1. Subjects

Reference individuals selected from among healthy persons on the basis of certain criteria are used as the parent population for setting the reference intervals[4]. The present study used urine specimens of 684 children (275 males and 409 females) who had undergone the secondary urinalysis test in primary schools and middle schools of the Hida area in 2008. The age distribution of the subjects is shown in ***Table 1***. The urinalysis system differs slightly from one area to another. In the Hida area, it is conducted as a part of a kidney screening program, according to the urinalysis system of the Gifu Prefecture. In the primary testing, dipstick tests for protein, occult blood, and glucose are performed by an automated urine analyzer. Subjects who are positive in the primary test are later tested in the secondary urinalysis.

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Table 1 *Breakdown of study subjects by gender and grade*

Age distribution (7 - 15 y. o.)	Males	Females
Primary School Grade 1	22	50
Primary School Grade 2	23	41
Primary School Grade 3	21	35
Primary School Grade 4	19	35
Primary School Grade 5	15	53
Primary School Grade 6	23	50
Middle School Grade 1	46	59
Middle School Grade 2	54	47
Middle School Grade 3	52	39
Total	275	409

2. Methods

The first morning urine was analyzed with the UF-1000*i* within 3 to 5 hours of collection. If the apparatus indicated a "Review" because the result was of low reliability due to analytical limitations, the specimen was excluded from the population used for determining the clinical reference interval. The calculation was done using a program based on the CRR method (Clinical Reference Range). The frequency distribution was calculated for each gender and the reference interval obtained. Parametric methods, nonparametric methods, and the CRR method are used as the statistical methods for determining the reference intervals, depending on the characteristics of the parent population. The CRR method is used when the inclusion of abnormal values has a certain probability. The upper and lower limits of the reference interval are obtained in the CRR method. But with analysis parameters like urine particle counts, the lower limit has no clinical significance, as the normal value should basically be zero, and therefore, we used only the upper limit reference value.

RESULTS

Frequency distribution (***Fig. 1***) and the upper limits of the reference interval (***Table 2***) of the analysis parameters RBC, WBC, EC, CAST, and BACT are shown below. The calculated reference values for RBC, WBC, EC, CAST, and BACT, were respectively 11.6, 5.8, 4.8, 0.27, and 3.4 / µL for males and 19.1, 9.2, 7.7, 0.25, and 34.8 / µL for females. Thus, females had higher values for all the analysis parameters except CAST.
The reference values for the research parameters of UF-1000*i* (crystals (X'TAL), yeast-like cells (YLC), small round cells (SRC), pathological casts (Path.CAST), mucus (MUCUS), and spermatozoa (SPERM)) were also determined (***Table 3***), as reference information. The reference values for SRC, Path.CAST, and MUCUS, were respectively 3.8, 0.17, and 0.6 / µL for males, and reference values for X'TAL, SRC, Path.CAST, and MUCUS, were respectively 0.1, 4.5, 0.17, and 0.6 / µL for females. Parameters other than those were not detected in the males and females.

DISCUSSION

The reference values of the parameters of 684 school-children subjected to secondary urinalysis in school health checkup generally tended to be higher in females than in males. The possible major reason for this includes contamination at the time of urine collection. A similar trend was reported in adults also[3]. There is a report that abnormal urinalysis results were more frequent among females[5]. The results of the present study appear to support this. The values of most of the research parameters, which are aimed at detecting pathological components, were near zero in the present study. Age-wise comparison of the mean values of each parameter did not show any statistically significant differences (data not shown). Comparison of the results obtained here with those obtained with UF-100, an earlier model of the fully automated urine particle analyzer[6], showed similarity in all the values except for BACT. UF-1000*i* has improved bacteria detection capability because of its dedicated bacteria channel. This must be the reason for the observed difference in BACT.
Common kidney diseases of pre-school and school age children are acute and chronic nephritis, IgA nephropathy, purpura nephritis, and nephrotic syndrome[7]. Early detection of these diseases, monitoring of progress, guidance on disease management, and prompt starting of treatment are of major significance. We believe that the results obtained in the present study would be useful as reference data for diagnosis of these diseases and for setting review criteria for the use of this analyzer. In interpreting the results, it is necessary to also take into account the method of urine collection, changes

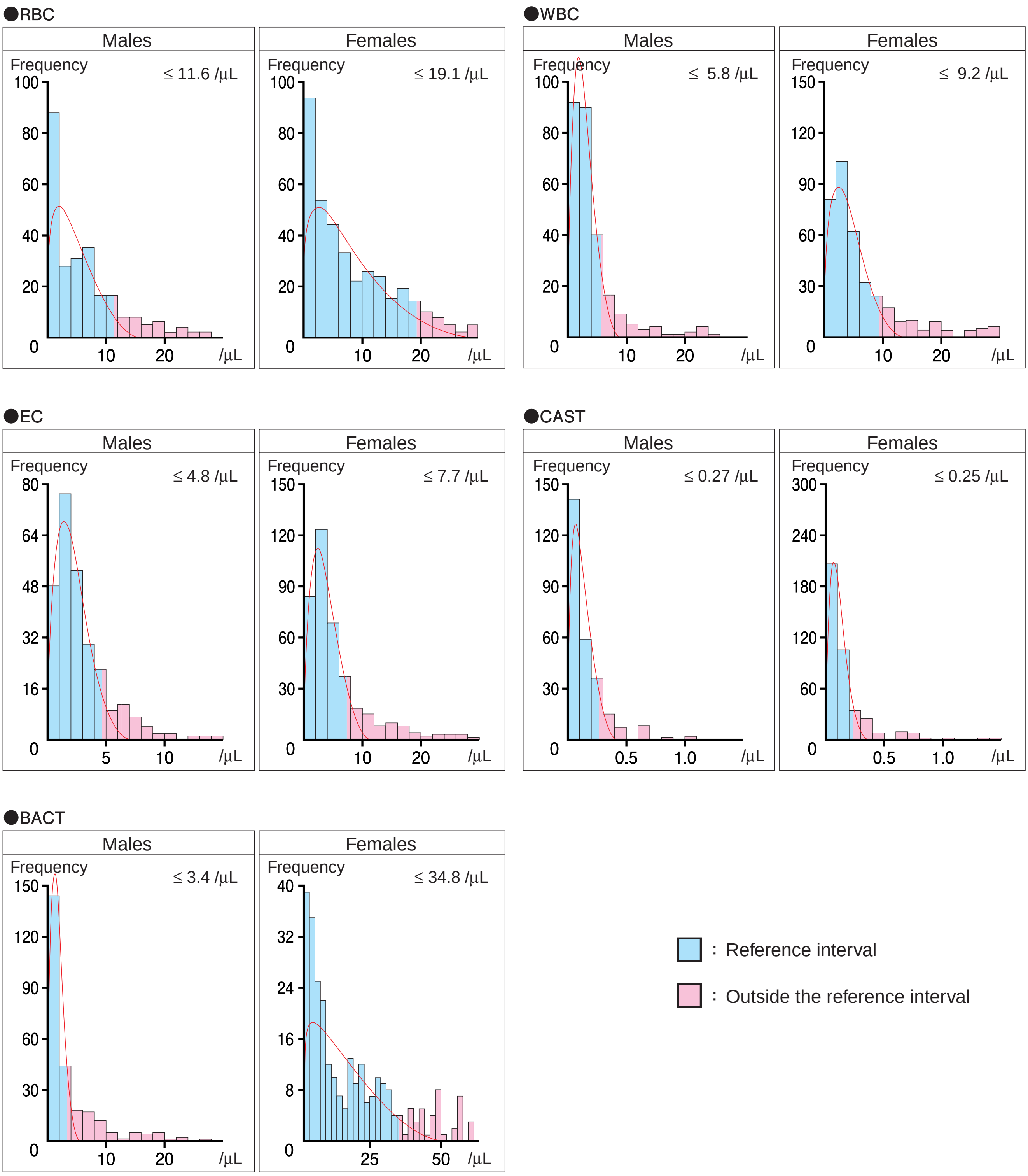

Fig. 1 Frequency distribution by gender of analysis parameter values of urine particles analyzed with UF-1000i

Table 2 *Analysis parameters of UF-1000i, and gender-wise reference values for the 7 to 15 age group*

	RBC	WBC	EC	CAST	BACT
Overall	16.3	8.0	7.1	0.26	20.7
Males	11.6	5.8	4.8	0.27	3.4
Females	19.1	9.2	7.7	0.25	34.8

(Unit: μL)

Table 3 *Research parameters of UF-1000i, and gender-wise reference values for the 7 to 15 age group*

	X'TAL	YLC	SRC	Path. CAST	MUCUS	SPERM
Overall	0.1	ND	3.9	0.17	0.6	ND
Males	ND	ND	3.8	0.17	0.6	ND
Females	0.1	ND	4.5	0.17	0.6	ND

(Unit: μL)

with time in the specimen before the measurement, regional differences related to diet and climate, etc, all of which affect the urine sediment components. The reference intervals are set as yardsticks for understanding the variation in laboratory test values, and are not the limits for separating abnormal from normal values or for deciding whether a subject has a certain disease[4]. Therefore, the final decision regarding the presence of a disease has to be made on the basis of a comprehensive evaluation of other findings about the patient, and taking into account the aforementioned conditions at the time of testing.

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